AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 64

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50120C00097	See Block 20C	OS257445

5. ISSUED BY	CODE	6. ADMINISTERED BY *(If other than Item 5)*	CODE
DHHS/ASPR-BARDA Division of Contract Management & Acquisition 200 C Street, SW, 2nd Floor Washington, DC 20515-0001	DHHS/ASPR-BARDA		SCD-C

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
PHILIPS NORTH AMERICA LLC 113528 Attn: JAMES PHILIPS NORTH AMERICA LLC 2 CA 2 CANAL PARK 3RD FL CAMBRIDGE MA 021412232	☐ FOB ORIGIN ☒ OTHER *(See below)*	

CODE	FACILITY CODE	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM
113528			

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201	HHS/OS/ASPR		

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a) ( )

14. ACCOUNTING AND APPROPRIATION DATA
2020.1992020.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT $34,893,033.36

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	B	SUPPLIES OR SERVICES AND PRICES/COSTS				PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
	C	DESCRIPTION/SPECS./WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS	
	E	INSPECTION AND ACCEPTANCE			K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	F	DELIVERIES OR PERFORMANCE					
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☐ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return_____copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☒ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Joseph J. Frassica, M.D., Head Philips Research NA	

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
Philips Research, a div. of Philips N America LLC	5/7/2020	BY James P. Bowers -S	Digitally signed by James P. Bowers -S DN: c=US, o=U.S. Government, ou=People, 0.9.2342.19200300.100.1.1=2000815283, ou=HHS, ou=OS, cn=James P. Bowers -S Date: 2020.05.08 09:14:23 -04'00'
BY DocuSigned by: Joseph J. Frassica, MD, FAHP, FICP *(Signature of person authorized to sign)*		*(Signature of the Contracting Officer)*	

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

PHILIPS NORTH AMERICA LLC 113528

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 13-3429115 DUNS Number: 013691415 ASPR-20-01892 -- Base period funds to Philips Research a Division of Philips North America LLC Delivery: 04/16/2020 Appr. Yr.: 2020 CAN: 1992020 Object Class: 25106 FOB: Destination				
1	ASPR-20-01892 -- Base period funds to Philips Research a Division of Philips North America LLC Obligated Amount: $34,893,033.36				34,893,033.36

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PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) and was reauthorized under the PAHPA of 2013 to support development and acquisition of medical countermeasure (MCMs) to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

Philips Research, a Division of Philips North America LLC, is developing an artificial intelligence (AI) enabled multifunctional hand-held system (*"An AI-Based Multi-Functional Hand-Held Lumify Ultrasound for Automatic and Intelligent Quantitative Assessment of Lung Injuries, Diseases and Traumatic Injuries in a Mass-Casualty Incident"*). This contract from BARDA supports development of this multifunctional hand-held ultrasound system platform and next generation transducers outlined below. It is envisioned that this hand-held ultrasound system would be used and integrated within routine care for burns and traumatic injuries, but would also have significant advantages in a mass casualty incident. Furthermore, the multi-functionality of the Lumify ultrasound machine platform, will expand and enhance its sustainability and marketability when integrated into the US health care system.

(b) (4)

(b) (4)

(b) (4)

BARDA is seeking $34.9M for conducting the advanced research and development described in the statement of work (SOW) within the BASE period beginning in FY20.

The Government has determined a Bona Fide Need for each non-severable discrete work segment which will conclude upon the completion of a defined task or defined tasks that provide(s) independent merit and value to the Government. The Contractor's success in completing the required tasks under the work segments must be demonstrated through the Deliverables and Milestones specified under Article F of this contract. As set forth in the Contract WBS Milestones/Deliverables and Technical Deliverables chart under Article F of this contract, the GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option period(s).

The base and option period segments under Contract Line Item (CLIN) 0001, CLIN 002, and CLIN003 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, shall only be used for the scope of work covered in each discrete work segment (i.e., the base period work segment and each option work segment). The periods of performance listed under each of the CLINs under Article B.2 and Article B.3 below are estimated time periods. Those individual time periods may be extended to complete the tasks required under each work segment. It is possible that more than one option period (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently.

B.2 BASE PERIOD

1. The total estimated cost of the base period of this contract, (b) (4) (b) (4) $34,893,033.

2. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 (Oct 2010), Audit and Records – Negotiation and incorporated by reference into the contract in SECTION I.

3. The amount currently obligated will cover base performance of the contract through May 31, 2023. The period of performance may be adjusted with mutual agreement.

CLIN	Period of Performance	Supplies/Services	(b) (4)	(b) (4)	Not To Exceed
0001	Base Period 5/8/2020 through 5/31/2023	Smoke Inhalation: Market Research Study, Pre-clinical & POC Clinical Studies, Algorithm Development, includes Ultrasound for Infectious Diseases	(b) (4)	(b) (4)	$10,996,717

0002	Base Period 5/8/2020 through 5/31/2023	FAST Exam: Pre-clinical & POC Clinical Studies, Algorithm Development, Development of First Working Prototype and Engineering Prototype of Novel 3D Transducer	(b) (4)	(b) (4)	$19,867,351
0003	Base Period 5/8/2020 through 5/31/2023	Compartment Syndrome: POC Clinical study	(b) (4)	(b) (4)	$4,028,965
	TOTAL BASE		(b) (4)		$34,893,033

B.3. OPTION PERIODS

B.3.1 COST REIMBURSMENT OPTIONS

a. The contract includes optional, cost reimbursement CLINs 0004, 0005 and 0006. The Government may exercise Option Periods in accordance with FAR 52.217-9 Option to Extend the Term of the Contract (March 2000), as set forth in Section I of the contract.

b. Unless the government exercises its option pursuant to the option clause contained in ARTICLE I.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTONS C and F, for the price set forth in ARTICLE B.2 of the contract.

c. The Government may modify the contract unilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with FAR 52.217-9.

d. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The tentative time frame for period of performance and estimated cost of the contract will be increased as set forth below

OPTION	CLIN	Period of Performance	Supplies/Services	(b) (4)	(b) (4)	Not to Exceed Total
1	0004	Option Period 5/31/2023 through 5/31/2025	Option 1 Period (Smoke Inhalation): Prospective Clinical Validation Study, SI Lung Product Development	(b) (4)	(b) (4)	$6,335,931

2	0005	Option Period 5/31/2023 through 5/31/2025	Option 2 Period (FAST Exam): Prospective Clinical Validation Study, FAST Exam System Product Development	(b) (4)	(b) (4)	$9,792,725
3	0006	Option Period 5/31/2023 through 5/31/2025	Option 3 Period (Compartment Syndrome): Prospective Clinical Validation Trial	(b) (4)	(b) (4)	$2,309,599
		TOTAL OPTIONS				$18,438,255
		TOTAL	BASE PLUS OPTIONS			**$ 53,331,288**

B.5. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer or set forth in the Statement of Work, the cost of the following items or activities shall be unallowable as direct costs:

1) Acquisition, by purchase or lease, of any interest in real property;

2) Special rearrangement or alteration of facilities;

3) Accountable Government Property (see the HHS Contracting Guide for Control for Government Property incorporated by Section G.9. of this contract);

   Note: this includes the lease or purchase of <u>any</u> item of general purpose office furniture or office equipment regardless of dollar value.

4) Purchase or lease of scientific instruments or equipment over $10,000 except for instruments and equipment specifically included in the Statement of Work;

5) Travel to attend general scientific meetings/conferences;

6) Printing Costs (as defined in the Government Printing and Binding Regulations);

7) Overtime (premium) compensation

8) Entering into certain types of subcontracting arrangements (See Section B.5(c) for specific obligations). Note that most consulting agreements require CO's written consent.

9) Foreign Travel (see Subparagraph b.3);

10) Patient care costs (see Section J-List of Attachments);

11) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

b. Travel Costs

1) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract during the Base Period (CLIN 0001) shall not exceed $114,572 without the prior written approval of the Contracting Officer. The Contractor shall notify the Contracting Officer in writing when travel expenditures have exceeded 80% of the base period travel expenses. Costs must be consistent with Federal Acquisition Regulations (FAR) 52.247-63 – Preference for U.S. Air Flag carriers.

2) Subject to the dollar limitation specified under B.5.b.1. above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2 – Contracts with Commercial Organizations, Sub-Section 31.205- 46, Travel Costs.

3) If foreign travel is necessary, a Contracting Officer Authorization (COA) will be required. Expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed the amount specified in each approved COA, without the prior written approval of the Contracting Officer.

   Requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

   - Meeting(s) and place(s) to be visited, with costs and dates; name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
   - Contract purposes to be served by the travel;
   - How travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of BARDA contract funds;
   - How such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
   - What additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

B.6. ADVANCE UNDERSTANDINGS

a. Person-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's or Subcontractor's facility, who shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

b. Security

No security plan is required at this point for this effort. It is anticipated that a security waiver will be approved.

c. Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type and exceeds $150,000; or
- Is of the fixed price type and exceeds $150,000 or 5% of the contract, whichever is less.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244- 2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section.

d. The following subcontracts are contemplated at time of contract award:

(b) (4) - The Prime Contractor is to enter into a subcontract (b) (4) , NC to generate the cost effectiveness analysis study and the budget impact modeling. A copy of this subcontract will be made a part of the contract file.

(b) (4) - The Prime Contractor is to enter into a subcontract (b) (4) (b) (4) to conduct the clinical studies for smoke

inhalation injury, FAST exam, and compartment syndrome. A copy of this subcontract will be made a part of the contract file.

(b) (4) - Philips is to enter into a subcontract (b) (4) (b) (4) , to develop the critical deep learning aspects of the algorithms for the lung injury and FAST exam ultrasound products. A copy of this subcontract will be made a part of the contract file.

(b) (4) –Philips is to enter into a subcontract (b) (4) (b) (4) for collection, curation, interpretation, and transmission of lung ultrasounds and accompanying data that will be performed primarily on patients with suspected or confirmed COVID-19 illness in the Hospital.

A Contracting Officer's Authorization will be required prior to these subcontracts.

e. Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract

f. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial information outside of the United States Government. Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

g. Approval of Human and Animal Protocols

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval prior to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

h. Rights in Data

The contract incorporates FAR Clause 52.227-14, Rights in Data—General. The Contractor should review the terms of this clause regarding the government's rights to deliverables submitted during performance and its rights to data in those deliverables.

i. **Invoice Submission during end of Fiscal Year**

The government will not accept invoices for processing from Sep 6th through Oct 5th because of end of year fiscal requirements. Any invoices received during that period will be canceled and returned to the Contractor for resubmission beginning Oct 6th.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work attached to this contract as Attachment 1 (Section J-List of Attachments).

C.2. REPORTING REQUIREMENTS

Refer to Section F.2 for specific instructions regarding Reporting Requirements.

C.3. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contract Officer, the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise mutually agreed upon by the Government and the Contractor or determined by the Contracting Officer. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded in eRoom by the Contractor within five (5) business days after the conference call is held.

C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may include face-to-face meetings with BARDA in Washington, D.C. and at work sites of the Contractor and subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and Government personnel as required by the COR in to facilitate review of contract activities.

a. **Kickoff Meeting**

The Contractor and Government shall conduct a kickoff meeting within 45 calendar days after contract award to review HHS procedures, processes and expectations. Contractor shall provide an itinerary/agenda no later than 5 business days before meeting. Minutes from the kickoff meeting must be provided within 10 business days of

the event.

b. Quarterly and Ad-Hoc Meetings

At the discretion of the CO or COR, the Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may be conducted via teleconferences or face-to-face meetings in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor's confidential or proprietary data) and Government personnel as required by the Contracting Officer's Representative, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least 2 business days in advance of face-to-face meeting.

Contractor shall provide a meeting summary to the BARDA COR no later than 5 business days after the meeting.

c. Face-to-Face Project Review Meetings

The Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC. The Contractor will be responsible for updating the BARDA program on technical progress under the Statement of Work. Presentation must be delivered seven (7) business days prior to the scheduled meeting.

C.5 RISK MANAGEMENT

The Contractor shall establish and maintain an active, enterprise-wide risk management system as well as a specific risk management plan that includes the SOPs governing risk management, a description of the risk management activities required to oversee the project across its range of scope, and the processes for reviewing completed risk mitigations. The Contractor shall complete risk management documentation for the program as applicable, such as:

1. Preliminary hazard analyses as necessary for each product component
2. Design, user, and process FMEA plans
3. Risk control plans to verify the proposed mitigations

C.6 REGULATORY ACTIVITIES

The Contractor shall provide the COR the opportunity to review and comment upon any draft documents, including draft pre-submission packages, and meeting requests, to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with five (5) business days for review and comments. An acceptable version shall be provided to the COR prior to FDA submission.

The Contractor shall provide the COR initial draft minutes and final draft minutes of any - meeting with the FDA and other regulatory agencies.

The Contractor shall communicate the dates and times of any meeting with the FDA and other regulatory agencies to the COR and ensure participation for appropriate COR and BARDA SME staff to attend the meetings.

The Contractor shall forward Standard Operating Procedures (SOPs) upon request from Contracting Officer's Representative /Contracting Officer.

The Contractor shall work to support BARDA in development of FDA submissions and meeting for seeking a Pre-Emergency Use Authorization if deemed necessary by BARDA. The support may require the Contractor to develop unique deliverables other than the ones related to the SOW for submission to the FDA by BARDA.

The Contractor shall support FDA audits. Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

C.7 QUALITY

The Contractor shall establish and maintain a Quality Management System with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor shall establish routine internal reviews, documentation, and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor shall contract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition. Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. On request, the CO will make the full text available.

Also, the full text may be accessed electronically at: https://www.acquisition.gov/FAR (for FAR) and at: http://www.hhs.gov/policies/hhsar/subpart352.html. (for HHSAR)

FAR Clause **Title and Date**

FAR 52.246-3, Inspection of Supplies – Cost-Reimbursement (May 2001)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)
FAR 52.246-16, Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will take place at a location designated by the Contracting Officer or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority O'Neill
House Office Building
Washington, DC 20515

a. Site Visits and Inspections

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance:

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective

action(s) of the audit.

- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the Government exercises the Options Period(s) pursuant to the Option Clause in Section I.3 of the contract, the period of performance shall be increased as shown in the table in Section B.3.

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in the Statement of Work dated September 10, 2018, set forth in Section J - List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the COR, of each of the deliverables described in Section C, Section F, and Section J.

All deliverables and reporting documents listed within this Section shall be delivered electronically (as defined in Section F.3 Electronic Submission) to the CO, CS, and the COR unless otherwise specified by the CO.

Unless otherwise specified by the CO, the deliverables identified in this Section F shall also be delivered electronically to the designated eRoom along with a concurrent email notification sent to the CO, CS, COR, and Alternate COR stating delivery has been made.

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). Hard copies of deliverables and reports furnished to the Government under the resultant Contract (including invoices) shall be addressed as follows:

HHS/ASPR/BARDA/CMA:

ATTN: James P. Bowers (Contracting Officer)
U.S. Department of Health & Human Services
Biomedical Research and Development Authority (BARDA)
O'Neill House Office Building
Room Number: 21B05
Washington, DC 20515
Email: james.bowers@hhs.gov

HHS/ASPR/BARDA:

ATTN: Janelle Hurwitz (COR)
U.S. Department of Health & Human Services
Biomedical Advanced Research & Development Authority (BARDA)
O'Neill House Office Building

Room Number: 24K09 Washington, DC 20515
Email: janelle.hurwitz@hhs.gov

Contract Data Requirements List (CDRLs)

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	▪ Within 45 calendar days after contract award. ▪ Materials: Contractor shall provide itinerary and agenda to CO and COR at least 5 business days in advance of meeting. CO approves and the COR distributes itinerary and agenda within 3 business days. ▪ Due out: Contractor provides meeting minutes to CO and COR within 5 business days after the meeting. The CO and COR reviews, comments, and the CO approves minutes within 10 business days of the event.
2	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or subcontractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	▪ Materials: Contractor shall provide itinerary and agenda to CO and COR at least 2 business days in advance of site visit. The COR approves and distributes itinerary and agenda within 2 business days. ▪ Due out: Contractor provides meeting minutes to the CO and the COR within 5 business days after the meeting. The CO and COR reviews, comments, and the CO approves minutes within 10 business days.
03	Biweekly Teleconference	The Contractor shall participate in teleconferences	▪ Materials: Contractor provides agenda to the

	Meetings	every two weeks with the CO and the COR to discuss the performance of the contract.	CO and COR no later than 2 business days in advance of meeting. The COR approves and distributes agenda prior to meeting. • Due out: Contractor provides meeting minutes to the CO and COR within 5 business days following the meeting. The CO and COR reviews, comments, and the COR approves minutes within 10 business days following the meeting.
04 (Monthly) 05 (Annual)	Monthly & Annual Technical Progress Reports	The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR). 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2-3 pages. 2. Progress in meeting contract milestones – broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining occurrences of any	• Due: Monthly Reports shall be submitted on the 25th day of the month after the end of each month with an Annual Report submitted on the 30th calendar day of the final month of each contract year for the previous twelve calendar months. • When the 25th or 30th falls on a weekend or a US Holiday, the reports will be due the next business day. • Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due. The CO and the COR will review the monthly reports and provide feedback within 5 business days of receiving the report. The CO approves acceptance of monthly and annual reports.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		differences between the two and the corrective steps. 3. The reports shall also include a three-month rolling forecast of the key planned activities, referencing the WBS/IMS. 4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps. 5. Estimated and Actual Expenses. 6. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	
06	Risk Management Plan	The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall	• Due: Within 90 days of contract award. • Due out: Contractor provides updated Risk Management Plan in Monthly Progress

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.	Report. The COR shall provide Contractor with written comments in response submitted plan. Contractor must address, in writing, all commercially reasonable concerns raised by the COR within 20 business days of Contractor's receipt of COR's concerns for CO approval.
07	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule. Contractor shall notify BARDA of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high-level management strategy for risk mitigation.	▪ Due: As needed and communicated by the COR/CO.
08	Go/No-Go In-Process Review (IPR) or Decision Gate Presentation	Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones following a prescribed template provided by BARDA prior to the IPR.	▪ Materials: Contractor shall provide presentation materials to the CO and COR 10 business days prior to the In-Process Review (IPR). Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria. After reviewing, the CO and COR will provide a written response within 10 business days.
09	Incident Report	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the CO and COR.	▪ Due: Within 48 hours of activity or incident or within 24 hours for a security activity or incident via email or telephone, with written follow-up to the CO and COR. Additional

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			updates due within 48 hours of additional developments. - Due out: Contractor shall submit, within 5 business days, a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO, within 5 business days of receiving such concerns in writing.
10	Draft and Final Reports for Clinical and Non-Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the CO and COR for review and comment.	- Draft - within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by Contractor. The CO shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within 15 business days after the submission. - Final - due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies. If corrective action is recommended, Contractor must address, in writing, all reasonable concerns

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			raised by the CO in writing. Contractor shall consider revising reports to address CO's recommendations prior to FDA submission. • Final FDA submissions shall be provided to the CO and COR concurrently or no later than 5 business days after submission to the FDA.
11	Standard Operating Procedures	The Contractor shall make internal and, to the extent possible, subcontractor Standard Operating Procedures (SOPs) available for review electronically.	Upon request from the CO.
12	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to the CO and COR. All documents shall be duly marked as either "Draft" or "Final".	• Due: Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.
13	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate government staff to attend the FDA meetings. Government staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).	• Contractor shall schedule upcoming FDA meetings, so at a minimum the CO, COR, and RQA persons from BARDA can attend. Additionally, a pre-meeting needs to be held with BARDA to review slides and discuss meeting strategies. • Contractor shall notify the CO and COR of upcoming FDA meeting within 24 hours of scheduling. • The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			and COR within 5 business days of receipt. All documents shall be duly marked as either “Draft” or “Final”.
14	FDA Submissions	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final”.	⬩ Due: Contractor shall submit draft FDA submissions to the CO and COR at least 15 business days prior to FDA submission. The CO and COR will provide feedback to Contractor within 10 business days of receipt. ⬩ Due out: If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the CO. ⬩ The Contractor shall consider revising their documents to address CO’s concerns and/or recommendations prior to FDA submission. ⬩ Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar day of its submission to CDER.
15	FDA Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and	⬩ Contractor shall notify the CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. ⬩ Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	contract or for this product within 5 business days of receiving correspondence from the FDA or third party. Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.
16	QA Audit Reports	BARDA Quality group and /or their qualified representatives reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	Contractor shall notify the CO and COR 10 days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. Contractor shall notify the CO and COR within 5 business days of report completion.
17	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the CO and COR. Contractor shall also accommodate any 'for cause' audit if and when there are	If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		potential issues identified in the program during the period of performance. Such issues include but are not limited to stability failures, GLP issues etc. If the CO, COR, Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the CO and COR.	business days of the audit. • Due out: The CO and COR will review the report and provide a response to the Contractor with 10 business days. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.
18	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.	• Contractor shall provide technical document within 10 business days of COR's request. Contractor can request additional time on an as needed basis. • If corrective action is recommended by the COR, the Contractor must address, in writing, concerns raised by the COR to the COR and CO in writing.
19	Raw Data or Data Analysis	Contractor shall provide raw data and/or data analysis to the CO and COR upon request. Contractor shall address and adjudicate all concerns from BARDA review of the data/analysis and amend the reports as required.	• Contractor shall provide data or data analysis to the CO and COR within 20 business days of request. • Contractor shall amend the reports if required and adjudicate all comments.
20	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the CO and COR for review prior to submission.	• Contractor must submit all manuscript or scientific meeting abstract to the CO and COR within 30 days for manuscripts and 15 days for abstracts. • Contractor must address in writing all

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			concerns raised by the CO and COR in writing. - Final submissions shall be submitted to the CO and COR concurrently or no later than five (5) calendar days after its submission.
21	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.	- With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO and COR has received and approved an advanced copy of any draft press release to this contract not less than 2 business days prior to the issuance of the press release. The CO shall reply with comments within 1 business day of receipt of the draft press release. Should no comments be forthcoming from the CO by end of the 1st business day, Contractor will be permitted to issue the press release - If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. - Any final press releases shall be submitted to the CO and COR no later than 1 (one) calendar day prior to its release.
22	Integrated Master Schedule (IMS)-Gantt	The Contractor shall provide an IMS including WBS, critical path, and milestones.	- Due: Contractor shall provide the draft IMS-Gantt within 90 days of

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report. • Contractor must address, in writing, all concerns raised by the COR in writing and provide response to the CO and COR.
23	Draft and Final Technical Progress Report	A Draft Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire contract PoP. The draft report shall be duly marked as 'Draft'. The Final Technical Progress Report incorporating feedback received from the CO and COR and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'.	• Due: Contractor shall provide a draft Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. • Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by the Contractor. • Due out: the CO shall provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report. •Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.
24	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study	• The Contractor will submit all proposed

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		Protocols to the COR for evaluation. (The CO and COR reserves the right to request within the period of performance a non-proprietary Study Protocol for distribution within the US Government.	protocols to the CO and COR at least 10 business days prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the CO and COR to the satisfaction of the COR before study execution and provide the CO and COR a revised draft protocol that addresses the CO's comments and requested changes. • After receiving the revised Study Protocol that satisfies the COR, the CO will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. • Contractor shall not proceed with any study protocol until the COR gives its approval and the Contractor has provided the CO and COR with a final and approved Study Protocol.
25	Clinical Study Status Update	Contractor shall provide COR with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC	• Update will be submitted by e-mail or other electronic format to be provided by the COR by the end of the 25th business day of each new month. • When the 25th falls on a weekend or US Holiday, the update will be due the next business day.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		review/approval/renewal. Contractor will provide proposed format for the COR's review and approval.	◦ Updates, to the extent they are available, will be presented during biweekly teleconferences. ◦ If no changes have occurred since the prior update only a simple statement that there is no new data is required.

NOTE: Pursuant to federal law, no Government personnel shall publish, divulge, disclose, or otherwise make known to any non-Government entity any Contractor data marked according to FAR 52.227-14, unless permitted to do so by law or regulation.

Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Section F of this contract, and in the Statement of Work, attached to this contract (see Section J-List of Attachments).

i. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this Section. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.

- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
  a. This Section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
  b. This Section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

  A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due. The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under Section F.2. of this contract. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE -
  A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance
  audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the Deliverables Chart in Section F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table (“Summary of Contract Deliverables”) under SECTION F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in Section F.2. of the contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary of salient results achieved during the performance of the contract.

v. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report and as related to activities funded under this contract.

vi. Periodic Document Review

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request

within the Period of Performance a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

vii. Risk Management Plan

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 180 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The COR shall provide Contractor with a written list of concerns in response plan submitted

Contractor must address, in writing, all concerns raised by COR within 20 business days of Contractor's receipt of COR's concerns.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. FDA Submissions

The Contractor shall provide the COR all documents submitted to the FDA. Contractor shall provide the COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.
- If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

- Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

iii. **FDA Audits**

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy

(non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. **Other FDA Correspondence**

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents to the appropriate folder on https://eroom.bardatools.hhs.gov/eRoom (“eRoom”) which is the designated Government file sharing system. The Government shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b) (2) (ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in Section G – Contract Administration Data.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (Aug 1989)

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:
James P. Bowers (Contracting Officer)
U.S. Department of Health & Human Services
Biomedical Advanced Research and Development Authority (BARDA)
O'Neill House Office Building, Room Number: 21B05
Washington, DC 20515
james.bowers@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3) No information other than that which is contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.
4) The Government may unilaterally change its CO designation, and will notify the Contractor in writing of such change.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The Contracting Officer's Representative (COR) who will represent the Government for this contract is;
Janelle Hurwitz (COR)
U.S. Department of Health & Human Services
Biomedical Advanced Research & Development Authority (BARDA)
O'Neill House Office Building, Room Number: 24K09
Washington, DC 20515
Email: janelle.hurwitz@hhs.gov

The Alternate COR is:
Narayan Iyer, PhD (COR)
U.S. Department of Health & Human Services
Biomedical Advanced Research & Development Authority (BARDA)
O'Neill House Office Building, Room Number: 24K11
Washington, DC 20515
Email: Narayan.iyer@hhs.gov

The COR is responsible for:
1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3) Performing technical evaluation as required;
4) Performing technical inspections and acceptances required by this contract; and
5) Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
Joseph Frassica, MD	Head of Philips Research, Americas and Chief Medical Officer, Philips North America
Molly Flexman, PhD	Department Head of Ultrasound Imaging and Interventions, Philips Research
Kenton Gregory, MD	Director OHSU Center for Regenerative Medicine, Professor OHSU Department of Biomedical Engineering
Ben Wilson, PhD	IV Labs
Martha Wilson, MS	Product Manager
Deep Pal	Head of Regulatory Affairs for Philips Ultrasound
Balasundar Raju, PhD	Technical Project Manager, Philips

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government. At a minimum, the key personnel should include the project manager, principal investigator, radiation biologist, quality control manager, quality assurance director, regulatory lead, and manufacturing lead.

G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under Section J entitled, "Financial Report of Individual Project/Contract,".

f. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact:

CO	COR	PSC
James Bowers(Contracting Officer) HHS/ASPR/BARDA/CMA O'Neill House Office Bldg Room Number: 21B05 Washington, DC 20515 Email: james.bowers@hhs.gov	Janelle Hurwitz COR HHS/ASPR/BARDA O'Neill House Office Bldg Room Number: 24K09 Washington, DC 20515 202-205-5716 Email: Janelle.hurwitz@hhs.gov	PSC_Invoices@psc.hhs.gov & "e-Room"

The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

• The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

• The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

• The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

• The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

• As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

• Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

• The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

• The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

• No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

• If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

• Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

• If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

h. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

i. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.

j. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Oct 2008).

k. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $10,000.
5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out

amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $10,000.
10. G&A - Cite rate and amount.
11. Total Cost (and applicable cost-shared ratio)
12. Fixed Fee (if applicable)
13. Total Cost Plus Fixed Fee

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

(i) Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest

equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.6. INDIRECT COST RATES

The following provisional billing rates are incorporated into the contract, and will be utilized for billing purposes during the Base Period (CLIN 0001) pending the establishment of final indirect cost rates for each fiscal year or until revised by the CO in accordance with the provisions of FAR 42.705-1.

Rate Type	(b) (4)	**Allocation Base**
Fringe Benefits	(b) (4)	Applied to labor (% 0f effort)
G&A	(b) (4)	Applied to total cost (excluding direct labor (% of effort) and fringe benefits (% of effort) and subcontracts
Overhead	(b) (4)	Applied to labor (% of effort)

Use of the above provisional rates does not change any cost ceilings, contract obligations, or specific allowance or disallowance provided for in the contract. Final rate proposals must be sent to the CO, within 6 months subsequent to the fiscal year end. (See also FAR Clause 52.216-7 incorporated herein).

G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

https://archive.org/details/contractorsguide00unit

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is attached to this contract (see Section J- List of Attachments). Title will vest in the Government for equipment purchased as a direct cost.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed-down as applicable.

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Section F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Section F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary. Important information regarding performing human subject research is

available at https://www.niaid.nih.gov/research/clinical-research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. **Non-Clinical Terms of Award**

a. These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non-clinical research and Safety and Monitoring Issues

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol.
They must also provide BARDA initial and annual documentation of continuing review and approval and federal wide assurance number.

The Contractor must ensure that the application, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
- All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).
- Termination or temporary suspension of the study(ies) for regulatory issues.
- Termination or temporary suspension of the protocol.
- Any change that is made in the specific IACUC approval for the indicated study(ies).
- Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify BARDA of any of the above changes within five (5) working days from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. **Non-Clinical Data and Safety Monitoring Requirements. BARDA strongly recommends continued safety monitoring for all non- clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. Awardee should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA- sponsored studies of any type measure the risk and safety parameters that are elicited and provide a safety profile from the studies for future human risk assessment.**

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CRO's as BARDA deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by BARDA:

- IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
- For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
- Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
- Contractor should reduce the number of animals required for a study using power of statistics.
- Plans for the management of side effects, rules for interventions and euthanasia criteria.
- Procedures for assessing and collecting safety data were appropriate.
- If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure anintegrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).
- Documentation that the Contractor and all required staff responsible for the conduct of the

research have received training in the protection and handling of animals, or that the CRO has the required documentation.

- Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract.

- Provide justification for whether studies require good laboratory practice (GLP) conditions.

- Provide justification for whether studies will be classified as non-pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to BARDA for evaluation and comment in conjunction with the protocol. Execution of non- clinical studies requires written authorization from BARDA in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals:
http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf

USDA Animal Welfare Act:
http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=3&tax_subject=182&topic_id=1118&level3_id=6735&level4_id=0&level5_id=0&placement_default=0

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Government and the Contractor; they apply to all grants and contracts that involve clinical research.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Within 30 days of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor

must provide the COR copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify the COR and CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if
any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102l).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following.

- **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee**

(SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

- **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

iii. **BARDA Protocol Review Process Before Patient Enrollment Begins** The COR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this Section of this contract.

iv. **Investigational New drug or Investigational Device Exemption Requirements**

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written

comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's Representative (COR) as follows:

i. Expedited safety report of unexpected or life-threatening experience or death:
A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

ii. Expedited safety reports of serious and unexpected adverse experiences: A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification. For medical devices, adverse events should be reported under the MedWatch (MDR) program with reporting timelines of 5 days for serious adverse events or 30 days for reportable events.

iii. IDE reports of unanticipated adverse device effect:

A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the COR within 24 hours of FDA notification.

iv. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

v. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) business days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

vi. Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the COR and the Contractor.

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current federal wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FW' via designation as agents of the institution of via individual investigator agreements (see OHRP website at: http//:www.hhs.gov/ohrp/policy/guidanceonalternativeofwa.pdf).

d. If at any time during the performance of this contract, the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of
45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800- 447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS HOTLINE
P.O. Box 23489 Washington, D.C. 20026

H.6. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.7. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.8. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.9. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, and that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full

disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.10. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.14. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded or furnished without proprietary restrictions under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.15. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition,

the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00097."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No.."

H.17. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive- legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature

itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-
legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the
advocacy or promotion of gun control.

H.18. PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

H.19. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.20. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for

addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.21. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.22. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.23. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

H.24. DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical Sections for which the contractor can assert a copyright under FAR Clause 52.227-14 I no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical Section, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the Section prior to publication.

H.25. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/regulations.html

H.26. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.27. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H.28. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.29. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.30. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.
b. The Contractor shall not use any funds obligated under this contract for the following:
    i. The creation of a human embryo or embryos for research purposes; or
    ii. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
c. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

H.31. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.32. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate

objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

PART II SECTION I CONTRACT CLAUSES

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Cost-Reimbursement Research and Development Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause	Date	Clause Title
52.202-1	Nov 2013	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
52.203-7	May 2014	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
52.203-14	Oct 2015	Display of Hotline Poster(s)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
52.204-1	Dec 1989	Approval of Contract
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
52.204-5	Oct 2014	Women-Owned Business (Other Than Small Business)
52.204-7	Oct 2018	System for Award Management
52.204-10	Oct 2018	Reporting Executive Compensation and First-Tier Subcontract Awards

52.204-13	Oct 2018	System for Award Management Maintenance
52.204-16	Jul 2016	Commercial and Government Entity Code Reporting
52.204-17	Jul 2016	Ownership of Control or Offeror
52.204-18	Jul 2016	Commercial and Government Entity Code Maintenance
52.207-1	May 2006	Notice of Standard Competition
52.209-5	Oct 2015	Certification Regarding Responsibility Matters
52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
52.210-1	Apr 2011	Market Research
52.211-5	Aug 2000	Material Requirements
52.215-2	Oct 2010	Audit and Records – Negotiation
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-16	June 2003	Facilities Capital Cost of Money
52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits(PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Aug 2018	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Oct 2018	Utilization of Small Business Concerns
52.219-9	Mar 2020	Small Business Subcontracting Plan
52.219-10	Oct 2014	Incentive Subcontracting Program
52.219-14	Mar 2020	Limitations on Subcontracting
52.219-16	Jan 1999	Liquidated Damages – Subcontracting Plan
52.219-28	Mar 2020	Post-Award Small Business Program Representation
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
52.222-25	Apr 1984	Affirmative Action Compliance

52.222-26	Sept 2016	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans
52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Jan 2019	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification
52.222-62	Jan 2017	Paid Sick Leave Under Executive Order 13706
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.225-25	Aug 2018	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-3	Apr 1984	Patent Indemnity
52.227-11	May 2014	Patent Rights – Ownership by the Contractor
52.227-14	May 2014	Rights in Data – General
52.227-14 Alt. II	Dec 2007	Rights in Data – General – Limited Rights Notice
52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
52.227-16	June 1987	Additional Data Requirements
52.228-7	Mar 1996	Insurance – Liability to Third Persons
52.230-2	Oct 2015	Cost Accounting Standards
52.230-3	Oct 2015	Disclosure and Consistency of Cost Accounting Practices
52.230-6	Jun 2010	Administration of Cost Accounting Standards
52.230-7	Apr 2005	Proposal Disclosure—Cost Accounting Practice Changes
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment
52.232-33	Jul 2013	Payment by Electronic Funds Transfer–System for Award Management
52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs

52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes – Cost-Reimbursement Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Aug 2019	Subcontracts for Commercial Items
52.245-1	Jan 2017	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protégé Program
HHSAR	352.219-71	Dec 2015	Mentor-Protégé Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of end of period of performance.

FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

The Government may extend the term of this contract by written notice to the Contractor within 15 days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

- If the Government exercises this option, the extended contract shall be considered to include this option clause.

- The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

FAR Clause 52.219-28, Post-Award Small Business Program Representation (Mar 2020)

a. *Definitions* As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates,that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e)of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [ ] is, [X] is not a small business concern under NAICS Code 541714 assigned to contract number .

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

“Covered contractor information system” means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

“Federal contract information” means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

“Information” means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

“Information system” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

“Safeguarding” means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated 04/28/2020, 33 pages

2. Invoice/Financing Request Instructions for AMCG Cost-Reimbursement Type Contracts,

Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Type Contracts, 2 pages.

3. Sample Invoice, 1 page

4. Financial Report of Individual Project/Contract, 1 page

5. Instructions for Completing Financial Report of Individual Project/Contract, 2 pages

6. Inclusion Enrollment Report

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

7. Research Patient Care Costs

Research Patient Care Costs, 1 page.

8. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property,1 page. Located at: http://rcb.cancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf

Attachment 1
Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement (BAA)
(BAA-18-100-SOL-0003)
April 28, 2020

An AI-Based Multi-Functional Hand-Held Lumify Ultrasound for Automatic and Intelligent Quantitative Assessment of Lung Injuries, Diseases and Traumatic Injuries in a Mass-Casualty Incident

Area of Interest Number (6.2 Smart Imaging System)

Contractual Statement of Work

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Background

The BARDA Intelligent Ultrasound is a multi-functional rapid triage tool for first responders in a mass-casualty event. The platform is based on the richness of the compact Philips Lumify, an Android-based hand-held ultrasound system. The project will build on the DARPA-funded automated detection and assisted diagnosis of pneumothorax, pneumonia and pleural effusion, and adds to it an automated smoke inhalation injury detection capability. Combined, these capabilities will serve as the Minimum Viable Product (MVP) that will reach the market and can be used in fire departments across the nation. In addition, Philips (the contractor) will develop and productize a novel 3D ultrasound transducer, enabling an even broader range of clinical applications, the first of which is an AI-based FAST Exam for rapid automated abdominal screening of trauma patients. As a critical, time-sensitive exam, FAST is useful in mass-casualty incidents. Finally, the contractor will conduct a Phase one clinical study of an ultrasound-based Compartment Syndrome diagnosis tool. In order to develop a commercially viable multi-functional product, the contractor has taken the approach to develop an MVP first, and then to add to it trauma care (abdominal and extremities) functionalities. Note that while out of scope for the current contract, the 3D ultrasound transducer can be used for other applications, including those

within cardiology, such that its commercial viability is strengthened. The contractor will work closely with its subcontract partners on all clinical and pre-clinical activities.

Overall Objectives and Scope

The overall objective of this contract is to advance the development of BARDA Intelligent Ultrasound as a rapid triage tool for first responders in a mass-casualty event. The R&D effort for the BARDA Intelligent Ultrasound will progress along three product tracks to be labeled Contract Line Item Number (CLIN) 0001 that covers Lung Ultrasound: automated smoke inhalation injury detection with an AI-based diagnostic assistance algorithm using a portable ultrasound and Lung Ultrasound Solution for Infectious Disease Management; CLIN 0002 that covers an automated AI-based FAST Exam enabled by a novel 3D ultrasound transducer; and a CLIN 0003 that covers a Compartment Syndrome diagnostic tool that uses ultrasound. The scope of work is broken into the following products and option(s) (CLINs) respectively, with each having a discrete work segment:

- Program Management: Overall management of the three products
- **(CLIN 0001)** Product 1 – Lung Ultrasound: Automated smoke inhalation (SI) injury detection with an AI-based diagnostic assistance algorithm for use with a hand-held ultrasound, includes,
    - Lung Ultrasound Solution for Infectious Disease Management (such as Viral Pneumonia)
    - Cost Effectiveness Analysis Study and Budget Impact Modeling
- **(CLIN 0002)** Product 2 - Fast Exam (FE): Automated FAST Exam enabled by the development and productization of a novel 3D ultrasound transducer and AI-based diagnostic assistance algorithm
- **(CLIN 0003)** Product 3 - Compartment Syndrome (CS): Clinical study for compartment syndrome diagnosis using a portable ultrasound

The scope of work for this contract for each Product consists of: Summary of Contract Deliverables; Pre-Clinical Data Collection Activities; Clinical Studies; AI-Algorithm Development Activities; Integrated Product Development with associated Quality Assurance, and Regulatory Activities. Tasks labeled "SI#," "FE#," "CS#" are identified in detail in the Work Breakdown Structure (WBS) and are used to summarize task level costs. The approach detailed in the full proposal is cross referenced here for instance with labels "SI Task #."

1. Program Management (WBS #1.1)

The contractor shall provide the following as outlined below and in the contract deliverables list.

1.1. The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

1.2. The Principal Investigator (PI) is ultimately responsible for execution of the SOW and expenditure of the budget via project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including

projects undertaken by subcontractors. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

1.3. The Project Manager (PM) responsible for monitoring and tracking day-to- day progress and timelines; coordinating communication and project activities; and managing costs incurred; as well as the overall program and contract deliverables list that identifies all contract deliverables and reporting requirements for this contract;

1.4. Administrative and legal staff with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract; and

1.5. Administrative staff with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors.

1.6. Contract Review Meetings;

- The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO and COR. Such meetings may include, but are not limited to, meeting of the contractors and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the contractor; and

- The contractor shall participate in biweekly teleconferences with the CO and COR to discuss the performance of the contract. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

1.7. Integrated Master Schedule (IMS)

- Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated IMS to the CO and COR for review and comment. The IMS shall be incorporated into the contract and will be used to monitor performance of the contract. The contractor shall include the key milestones and Go/No-Go Decision Gates (see 1.1.9.2).

1.8. Integrated Master Plan (IMP)

- Work Breakdown Structure (WBS): The contractor shall utilize a WBS template agreed upon by the government for reporting on the contract. The contractor shall expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by the government as part of their IMP for contract reporting. The CWBS shall be discernable and consistent. The CO

may require the contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

- Go/No-Go Decision Gates: The IMP outlines key milestones with "Go/No-Go" decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions.

- Project Management Plan: In the management of this contract, the contractor shall utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverables list (Sections 1.7, 2.7 and 3.7) for project management purposes. The contractor shall submit the project progress management report to the CO and COR on a monthly basis.

1.9. Decision Gate Reporting: Upon completion of a stage of the product development, as defined in the agreed upon IMS and IMP, the contractor shall prepare and submit to the CO and COR a Decision Gate Report that contains (i) sufficient detail, documentation, and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No-Go decision making; and (ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

1.10. Risk Management Plan: The contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three months) in the monthly Project Status Report (see 1.1.14).

Performance Measurement Baseline Review (PMBR): The contractor shall submit a plan for a PMBR to occur within 90 days of contract award. At the PMBR, the contractor and the government shall mutually agree upon the budget, schedule, and technical plan baselines (Performance Measurement Baseline [PMB]). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and adequately assigned resources. The goals of the PMBR are as follows:

i. Jointly assess areas such as the contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks;

ii. Confirm the integrity of the PMB;
iii. Provide confidence in the validity of contractor reporting;
iv. Identify risks associated with the PMB;
v. Present any revised PMBs for mutual agreement;
vi. Present an IMS; and
vii. Present the Risk Management Plan.

1.11. Deviation Request: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the contractor shall submit a Deviation Report. This report shall request a change in the agreed upon IMS and timelines that shall include: (i) discussion of the rationale/justification for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

1.12. Monthly and Annual Reports: The contractor shall deliver Project Status Reports on a monthly basis, that shall address the items below cross referenced to the SOW, WBS, IMS, and other Project Management Plan tool(s):

i. Executive summary highlighting the progress, issues, and relevant design, manufacturing, non-clinical, clinical, and regulatory activities;
ii. Progress in meeting contract milestones, detailing the planned and actual progress during the reporting period, explaining any differences between the two and corrective steps;
iii. Updated IMS;
iv. Updated Risk Management Plan (updated every three months);
v. Rolling forecast of planned activities (updated every three months);
vi. Progress of regulatory submissions; and
vii. Estimated and actual expenses.

1.13. Data Management: The contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

1.14. Provide for the statistical design and analysis of data resulting from the research; and

1.15. Provide raw data or specific analyses of data generated with contract funding to the CO and COR, upon request.

2. (CLIN 0001) PRODUCT 1: Lung Ultrasound (WBS #2.1)

The purpose of this task is to develop, and submit to the FDA for 510(k) clearance, a multi-functional hand-held Lumify device for automated image acquisition and interpretation during an AI-based smoke inhalation (SI) injury exam, and, lung infectious disease management. This task

enhances the pulmonary capabilities of the Lumify platform by adding a smoke inhalation injury detection capability to previously developed pulmonary capabilities: diagnosis of pneumothorax, pneumonia and pleural effusion, to achieve a Minimum Viable Product (MVP). Philips will conduct a thorough market research study on challenges faced by physicians (ER, Burn, Trauma) with patients with lung injury (smoke or other), which will help identify product gaps and specific attributes of smoke inhalation and lung injury in care that need to be addressed for a successful commercial smoke inhalation/injury diagnostic product.

Summary of Clinical Studies: Two studies are envisioned in the years 1-3 (base years): a pre-clinical study (8 animals SI2) and a clinical imaging collection study (137 patients, SI7-SI8). In years 4 and 5 (option years), an additional study (SI17-SI18) with 160 patients will be conducted. Please see Section 8 of this document for details of clinical studies. In addition, we will conduct a study to collect data on patients with infectious diseases at partnering clinical site (Yale University). A short paragraph on the approach for each study is presented below, and the list of CROs is also included.

- **STUDY 1. Pre-clinical Smoke Inhalation Injury: swine model for image acquisition, analysis, and correlation to pathology (SI Task 1a):** The preclinical swine studies of smoke inhalation injury allow precise iterative image acquisition under controlled conditions without confounding factors that can be present during human clinical imaging and will be done at MedStar Health Research Institute (MHRI) in the animal facilities in the George Hyman Research Building (GHRB). Briefly, after institutional approvals, smoke inhalation injury will be iteratively induced in eight anesthetized swine. CXR imaging, Lung Ultrasound (LUS) imaging, and blood sample collection will be performed prior to injury (baseline) and at several time points after injury. The LUS images will then be annotated using bounding boxes for the presence of several sonographic features and assessed in relation to a measurement of the lung's capability to oxygenate blood. After euthanasia, the lungs will be harvested, weighed and sectioned for histology and immunohistochemistry and compared to lung ultrasound findings.

- **STUDY 2a Proof-of-Concept Clinical Smoke inhalation lung injury feature discovery and image acquisition (Year 1):** An image collection study as described below will be undertaken, for 30 patients. This will serve as proof-of-concept.

- **STUDY 2b. Clinical Smoke inhalation lung injury feature discovery and image acquisition: (Years 1 and 2) (SI Task 2a):** This clinical image collection study will generate a high-quality image library of patients with inhalation lung injury relevant to those images to be attained at a mass casualty event. The study will enroll patients (n=137) at several sites including the US ARMY ISR Burn Unit at BAMC, Wake Forrest Burn Unit, Medstar Washington Hospital Burn Center, Tualatin valley Fire & Rescue, Portland Fire Dept, Oregon Municipal Fire Departments and US Forestry Service firefighting units based in Oregon. Patients with history of smoke inhalation and symptoms or findings of lung injury will be enrolled into IRB-approved studies (Human Research Protection Office approval as appropriate) after informed consent. Ultrasound of up to 14 lung zones using the Philips Lumify curvilinear transducer C5-2 will be performed by trained ultrasound clinicians. Patients with burns to the thorax will be imaged using sterile procedures during regularly scheduled dressing changes where anesthesia is normally performed so ultrasound transducer contact is not painful for the patient. Ultrasound images will be de-identified along with correlative clinical data, such as CXR, CT, and measures of oxygenation. Images with lung injury will be de-identified and transferred to OHSU, further annotated and used for algorithm development.

- **STUDY 3 FDA Prospective clinical trial to validate AI program and algorithm in patients with suspected smoke inhalation injury (Years 4, and 5) (SI Task 4a):** This study will perform an FDA approved prospective Clinical trial to validate the smoke inhalation algorithm in support of a 510k application. The sites involved include the US ARMY ISR Burn Unit at BAMC; Wake Forrest Burn Unit, Medstar Washington Hospital Burn Center, Tualatin valley Fire & Rescue, Portland Fire Dept, Oregon Municipal Fire Departments and US Forestry Service firefighting units based in Oregon. Patients referred to burn centers with history of smoke inhalation and symptoms or findings of lung injury will be enrolled into IRB-approved imaging studies (Human Research Protection Office approval as appropriate) after meeting inclusion criteria and signing informed consent. Out of hospital collection of images of patients will be attained using emergency fire and rescue responders at the site of fires in a metropolitan district and forest fires. Serial lung ultrasound data at several lung zones will be collected using the Philips Lumify C5-2 transducer daily. All correlative clinical data, O2 sat, vital signs, clinical observations, CO levels etc. along with relevant pulmonary data accumulated during transit and further evaluation (CXR, bronchoscopy, CT scanning) and treatments that are collected using current clinical practice will be obtained to correlate with LUS findings and summarized for FDA submission. Patient enrollment number is planned to be 160, but will be modified to power this study will be determined based on the finding from the earlier studies.

- **STUDY 4: Lung Ultrasound Solution for Pandemic Infectious Disease Management (Year 1):** A clinical study will be conducted at the Yale School of Medicine in support of developing a lung ultrasound solution for pandemic infectious disease management. Ultrasound data from about 50 patients with B-lines and/or pleural/subpleural changes obtained on patients with suspected or confirmed COVID, and 50 control patients without pleural changes will be collected. Ultrasounds will be performed at the bedside on subjects by either ultrasound experts (emergency physicians with fellowship training in ultrasound) or by a trained person with expert oversight. Each subject will have cineloop video clips recorded from multiple lung zones. These images will be de-identified, annotated and transferred to Philips for algorithm development.

Summary of AI Automation Algorithms: The contractor will modify an existing lung ultrasound AI model and retrain the algorithm to include features of, at first swine, and later human, smoke inhalation injury. Following these activities, the performance of the algorithm on sequestered data will be tested. In addition, an AI model for automated detection of B-lines for infectious diseases will be developed, based on annotated data of patients with lung infections.

Summary of FDA Meetings: Several meetings with the FDA are outlined. In year 1, after collecting clinical imaging data from 30 patients with smoke inhalation injury, the contractor will meet with the FDA to get its feedback on the clinical study protocol (SI7-SI8). In year 3, an FDA pre-510(k) meeting is planned. In year 4, for the third study (SI17-SI18), and after collecting data from 30 patients, another meeting with the FDA will take place in order to obtain feedback on the study.

Summary of Deliverables: To summarize the deliverables under 2.1 Contract Deliverables, an overarching view of the product deliverables timeline and workflow is, beginning in year 1 with the completion of the third party market research, and from year 1 to 3, completion of an animal lung ultrasound imaging study and of data collection in a human lung ultrasound imaging study along with annotation work and development of a lung AI algorithm development. At year 3 is a Go/No-Go meeting with BARDA.

By the time of the Go/No-Go decision, BARDA will have received materials for a FDA 510(k) pre-submission meeting, a report of the animal imaging and AI development, a curated library of annotated images of human smoke inhalation injury for machine learning, a CNN-based Al model for automated lung ultrasound image interpretation and detection of acute smoke inhalation injury in humans and a study protocol for a clinical validation trial for review and approval.

Should a Go decision be made, years 4 and 5 will entail completion of multi-center prospective clinical trial to validate the AI program and continued annotation work. By the end of year 4, an AI algorithm in patients with suspected smoke inhalation injury will be completed. In year 5, BARDA will receive commercially viable AI algorithms and a final report of the FDA prospective validation trial as well as a commercially viable software platform and prototype and the final system integration and a manufacturable product.

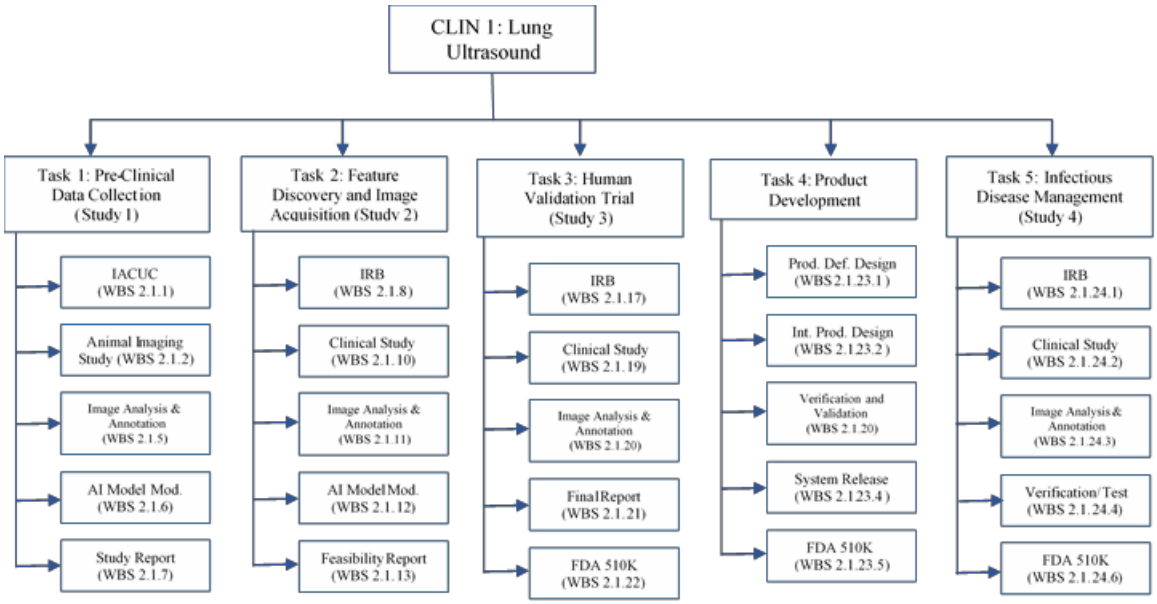

Figure 1: Activity Diagram Showing Key Activities in the Development of Lung Ultrasound Product

2.1 Contract Deliverables for PRODUCT 1: Lung Ultrasound

WBS Number	Unique Number	Deliverable Description	Year
2.1.23.1	SI-D-1	Market Research Report	Year 1
2.1.4	SI-D-2	Pre-clinical Smoke Inhalation Injury: swine model for image acquisition, analysis, and correlation to pathology (Study 1)	Year 1
2.1.5.8	SI-D-3	A library of annotated lung ultrasound images based upon the animal study, prepared for machine learning	Year 1
2.1.6	SI-D-4	A CNN-based Al model for automated lung ultrasound image interpretation and detection of acute smoke inhalation injury and an algorithm produced by supervised machine learning with a target of 90% sensitivity and specificity. This algorithm is anticipated to be produced by retraining an FDA approved algorithm created by our team.	Year 1
2.1.7	SI-D-5	A report of the animal imaging and AI development	Year 1

2.1.8	SI-D-6	Develop Clinical Trial Protocol and submit for IRB Review	Year 1
2.1.8.7	SI-D-7	Submit study protocol to BARDA for review and approval	Year 1
2.1.10.1	SI-D-8	Conduct an initial 30 patient POC study (Study 2a)	Year 1
2.1.10.2	SI-D-9	An FDA pre-submission meeting to get their feedback on study for automated detection of acute smoke inhalation injury based on initial 30 patient study (Study 2a)	Year 1
2.1.10	SI-D-10	Clinical Smoke inhalation lung injury feature discovery and image acquisition (Study 2b)	Year 2
2.1.11	SI-D-11	A curated library of annotated images of human smoke inhalation injury for machine learning.	Year 2
2.1.1.2.8	SI-D-12	Validate API/SDK Requirements and Software	Year 2
2.1.12	SI-D-13	Develop modification of existing lung ultrasound AI model and retrain the algorithm to include features of human smoke inhalation injury	Year 3
2.1.13	SI-D-14	Produce Preliminary report of feasibility of smoke inhalation AI in human data	Year 3
2.1.14	SI-D-15	Go/No-Go Meeting with BARDA, if "Go", proceed:	Year 3
2.1.15	SI-D-17	Produce and Submit materials in support of FDA Pre-Submission meeting to establish regulatory path for FDA allowance of algorithm for smoke inhalation injury stand alone	Year 4
2.1.17	SI-D-18	IRB Submission and approval for clinical validation trial	Year 4
2.1.17.18	SI-D-16	Submit study protocol to BARDA for review and approval	Year 4
2.1.19	SI-D-19	Completion of Multi-Center Prospective Clinical Trial to validate the Al program and algorithm in patients with suspected smoke inhalation injury (Study 3).	Year 4
2.1.21	SI-D-20	A final report of Prospective Validation Trial	Year 4
2.1.22	SI-D-21	Preparation and attendance of FDA pre-submission meeting to get their feedback on study for automated detection of acute smoke inhalation injury.	Year 4
2.1.23.3	SI-D-22	Delivery of commercially viable software platform and prototype	Year 5
2.1.23.4	SI-D-23	Delivery of commercially viable AI algorithms.	Year 5
2.1.23.5	SI-D-24	Final system integration and manufacturable product	Year 5
2.1.24.2	SI-D-25	A curated library of annotated images of human with respiratory infectious diseases for machine learning	Year 1
2.1.24.3	SI-D-26	An AI model for automated detection of B-lines for infectious diseases	Year 1
2.1.24.4	SI-D-27	Software for integration UI on Lumify	Year 1
2.1.24.5	SI-D-28	Lung Ultrasound solution for infectious disease management (Study 4)	Year 1
2.1.24.6	SI-D-29	Materials in support of an FDA 510k pre-submission meeting, attendance at this meeting and written response to the FDA.	Year 1
2.1.25.1	SI-D-30	Cost effectiveness analysis study	Year 1
2.1.25.2	SI-D-31	Budget impact models for SI and FAST are care cost and economic impact assessment	Year 1

2.1.25.3	SI-D-32	Return on Investment calculator	Year 1

2.2 Task 1: Pre-Clinical Data Collection

Subtask Purpose	Deliverables (Year)
Conduct an animal imaging study to collect data for AI algorithm development.	SI-D-2 – SI-D-5 (Year 1)

2.2.1 Pre-Clinical Smoke Inhalation Injury: swine model for image acquisition, analysis, and correlation to pathology (SI Task 1a)

- The contractor shall prepare and submit IACUC for animal imaging study (WBS 2.1.2/SI1)
- The contractor shall conduct animal imaging study (WBS 2.1.1/SI2)

2.2.2 Image Analysis and Annotation for Image Library for Machine Learning (SI Task 1b)

- The contractor shall perform image analysis and annotation of animal imaging study (WBS 2.1.5/SI3)
- The contractor shall develop modification of existing lung ultrasound AI model and retrain the algorithm to include features of swine smoke inhalation injury (WBS 2.1.6/SI4)
- The contractor shall produce a report of animal imaging study and AI development (WBS 2.1.7/SI5)

2.3 Task 2: Clinical Smoke Inhalation Lung Injury Feature Discovery and Image Acquisition (Study 2)

Subtask Purpose	Deliverables (Year)
Conduct a clinical study for acute smoke inhalation injury to gather image data for AI algorithm development	SI-D-6 - 14 (Years 1-3)

2.3.1 Clinical Smoke Inhalation Lung Injury Feature Discovery and Image Acquisition (SI Task 2a)

- The contractor shall prepare, submit and get approval from Institutional Review Board (IRB) for the human acute smoke inhalation injury imaging study for each of the following clinical sites: OHSU, BAMC, Medstar, Wake Forest, Portland Fire Department, US Forest Service (WBS 2.1.8/SI6)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.1.8.7)
- The contractor shall conduct clinical site training and initiate study for each of the

following clinical sites: OHSU, BAMC, Medstar, Wake Forest, Portland Fire Department, and US Forest Service (WBS 2.1.9/SI7)

- The contractor shall conduct a proof-of-concept acute smoke inhalation injury clinical imaging study (WBS 2.1.10/SI8/Study 2a).
- The contractor shall conduct a acute smoke inhalation injury clinical imaging study (WBS 2.1.10/SI8/Study 2b).

2.3.2 Image Analysis and Annotation for Image Library for Machine Learning (SI Task 2b)

- The contractor shall perform image analysis and annotation of clinical imaging study (WBS 2.1.11/SI9)

2.3.3 AI Algorithm Optimization (SI Task 2c)

- The contractor shall develop modification of an existing lung ultrasound AI model and retrain the algorithm to include features of human smoke inhalation injury (WBS 2.1.12/SI10)
- The contractor shall produce preliminary report of the feasibility of smoke inhalation AI in human data (WBS 2.1.13/SI11)

2.3.4 FDA Pre 510(k) Meeting (SI Task 3)

- The contractor shall produce and submit materials in support of FDA Pre-Submission meeting to establish a regulatory path for FDA allowance of algorithm for a smoke inhalation injury standalone app (WBS 2.1.15/SI13)
- The contractor shall present FDA Pre-Submission plan to FDA (WBS 2.1.16/SI14)
- The contractor shall provide a written response as a part of a FDA Pre-Submission meeting (WBS 2.1.17/SI15)
- Based on an initial 30 person study (Study 2a), the contractor shall meet with FDA in year 1 prior to clinical study (Study 2b) to get its feedback (WBS 2.1.10.2)

2.4 Task 3: Verification and Validation Of AI Inhalation Injury Algorithm: Human Clinical Trials (SI Task 4)

Subtask Purpose	Deliverables (Year)
Conduct a validation clinical study for acute smoke inhalation injury	SI-D-6 - 14 (Years 1-3)

2.4.1 Verification and Validation of AI Inhalation Injury Algorithm: Human Clinical Trials (SI Task 4)

- The contractor shall prepare, submit and get approval from the Institutional Review Board (IRB) for FDA clinical validation trial sites (WBS 2.1.17/SI16)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.1.17.18)
- The contractor shall initiate clinical site training for validation trial (WBS 2.1.18/SI17)
- The contractor shall conduct Prospective Clinical Trial to validate AI program and algorithm in patients with suspected smoke inhalation injury (WBS 2.1.19/SI18)

- The contractor shall perform clinical imaging annotation for acute smoke inhalation injury validation trial (WBS 2.1.20/SI19)

2.4.2 Smoke Inhalation FDA 510(k) Submission (SI Task 5)

- The contractor shall produce a final report of the FDA Prospective Validation Trial (WBS 2.1.21/SI20)
- The contractor shall prepare and submit a FDA 510(k) application for allowance of stand-alone algorithm for smoke inhalation injury (WBS 2.1.22/SI21)

2.5 Task 4: Integrated Product Development

Subtask Purpose	Deliverables (Year)
Integrated product development for acute smoke inhalation injury.	SI-D-12 (Year 2) SI-D-22 -24 (Year 5)

2.5.1 API Development (Foundation for SI and FE)

- The contractor shall develop architecture and design for API that will serve as the foundation for Smoke Inhalation and FAST Exam (WBS 2.1.1)
- The contractor shall implement and test the API (WBS 2.1.1)

2.5.2 Integrated Product Definition and Design; Integrated Product Integration and SI; Verification and Validation of Integrated Product (SI Task 6, 7 and 8)

- The contractor shall conduct detailed SI product development (SI22), that include
  - Product Definition and Design (VPA, PDC)
  - Integrated Product and Design (Product development, PLC)
  - Verification and Validation (SVER, SVAL)
  - System Release (RA, SR, RFD), and
  - Regulatory – 510(k) submittal

2.6 Task 5: Lung Ultrasound Solution for Infectious Disease Management (such as Viral Pneumonia)

Subtask Purpose	Deliverables (Year)
Rapid development and release of a solution for automated feature (B-lines) identification and quantification in lung imaging with Lumify.	SI-D-25 to 29 (Year 1)

Ultrasound use has numerous advantages in the management of infectious disease patients, including bedside diagnosis and avoidance of patient transport through a hospital (to a CT or other areas of the hospital) thereby minimizing infection spread, and the ability for longitudinal evaluation of progression and recovery over time. It is also conceivable that a mobile and easy-to-use ultrasound might enable at-home evaluation of patients to determine if the condition is severe enough for admission to the hospital or recommend an alternative course of action. Recent literature on lung ultrasound imaging of infectious disease patients points to specific features such as the presence of B-lines in a variety of patterns, thickening of pleural lines with irregularity, and the presence of consolidations. The evaluation of such features requires expertise that are not readily available. This work will aim to rapidly develop and release a solution for automated feature identification and quantification for lung imaging with Lumify. The specific task being addressed is the assessment of

B-lines which are the main feature observed in early stage and mild infection. The contractor (Philips) has access to lung ultrasound data with B-lines that were collected as part of other projects, enabling an immediate start of the project. Additional data collection on patients with infectious diseases will be collected at partnering clinical site. The contractor intends to submit the developed software as a measurement tool that does not require extensive clinical validation studies typically required of a CADx/CADe software, thereby enabling a faster solution for clinical uses.

As part of this level of effort, Philips will collaboratively work, as necessary, with one or more CRO(s) identified by BARDA to evaluate COVID or similar infectious disease animal models. As required, Philips (and participating CROs) would assist or educate in the use of ultrasound technology for use in the animal models for evaluation of infectious disease etiology. Philips (and participating CROs) will assist and participate in sharing information via publications and presentations.

2.6.1 Tasks (WBS 2.1.24) and Deliverables

The contractor shall provide the following as outlined below.

- IRB document preparation and submission for infectious disease management (WBS 2.1.24.1)
- Curate and annotate existing lung ultrasound datasets (months 1-3). With Clinical Site obtain data with annotation needed for project (months 1-6) (WBS 2.1.24.2)
- Develop image processing/AI methods for automated detection of B-lines for infectious diseases (months 1-6) (WBS 2.1.24.3)
- Develop software for integration UI on Lumify (months 5-10) (WBS 2.1.24.4)
- Lung ultrasound solution for infectious disease management (Study 4) (months 9-11) (WBS 2.1.24.6)
- Prepare regulatory documentation and submission (months 9-12) (WBS 2.1.24.7)
- Prepare clinical study report and/or publications, as required if the animal model studies are completed (WBS 2.1.24.8)

2.7 Cost Effectiveness Analysis Study and Budget Impact Modeling

This consists of three activities:

1. The cost effectiveness analysis study can serve as the foundation for the market access activities. It entails a deep literature review and close examination of the SI and FAST value propositions as assessed by healthcare payers.
2. The budget impact models for SI and FAST are care cost and economic impact assessment tool.
3. A “Return on Investment” (ROI) calculator, is a tool used by companies to engage in data-driven conversations with payers and decision-makers in healthcare.

These three activities will follow the third party market research outlined in the proposal.

2.7.1 Program Description

The work outlined here will provide a detailed analysis of how healthcare payers will value Philips’ proposed SI and FAST products. It will generate a comparison of current and alternative treatment scenarios in terms of cost, for a specific patient

population and over a defined period. The current and alternate scenarios will have differing market shares of treatments, thus leading to an associated budget impact.

This work will be executed by a well-qualified subcontractor with subject matter expertise in developing healthcare costs and economic impact assessment tools. The tool will enable financial scenario analysis related to mass-casualty incidents from the perspective of the proposed Philips products as well as alternative solutions.

There are multiple methods Philips uses internally and together with external partners to frame these research questions. One such methodology is PICOS:

P	Relevant Patient, Population, or Problem (Target)	Describe & define the patient target group; unmet clinical need; health inequality (Epidemiology; Etiology; Ethnicity)
I	Intervention (Offer)	Type: Screening; diagnostic test; treatment; preventive measure; …. Use of the product in the care pathway: Where (setting); Who (user); When is it used (e.g., before/after Tx); How often is it used. Dx test: what is the target condition the test aims to diagnose or exclude?
C	Comparison / Comparator (Alternatives)	What is the main alternative to compare with the intervention? = Current established practice; Standard of Care. Do you anticipate any new future comparators for your product? Consider: devices; drugs; service; disruptors.
O	Outcome/s (Benefits) Patient experience	What outcomes do I want to improve or affect and measure Dx test: Accuracy (test parameters); relevant direct & downstream measures
S	Source of Business	Impact on health system resources; reimbursement; contextual factors that may impact adoption, acceptance and/or implementation in a health system / Geography: •Does it require systemic / process / structure changes in a (national; local) Health System? What are the current ‘show stoppers’ at macro (health system) & meso (provider) level?

Once the study is completed, the contractor will move to develop the budget impact model. Done correctly, the tool would enable pointing out the advantages of adding the proposed SI and FAST solutions to other available therapies. The model will be populated with parameter estimates taken from the initial analysis study, and will incorporate feedback from BARDA, subject-matter experts in the field and external key opinion leaders.

The tool is expected to be self-standing, simple to use and include access to other

required information such as databases necessary for full functionality and use of the software. It shall also be compatible and integrate to other cost assessment modules previously created for BARDA (for example, products from other parts of burn care like skin substitutes, autograft sparing technologies, or visualization tools).

To conclude the program, the contractor is proposing to use the model as an external (customer-facing) tool, and to convert it into an app-based application that can be used in conversations with payers and decision-makers in healthcare.

2.7.2 ProgramManagement & Deliverables

The contractor shall provide the following as outlined below and in the contract deliverables list.

- The overall management and coordination of this work will be done by the contractor, including the management of any subcontractors (e.g. 3rd party analytics companies). The contractor will deliver a document outlining the goals, approach, milestones, timeline and key performance indicators.

- In a first phase, the contractor will deliver a literature review. The final review will be shared with BARDA in MS Word format.

- Following the literature review, the cost effectiveness analysis study will be completed. The final study will be share with BARDA in MS PowerPoint format. (WBS 2.1.25.1)

- In the second phase of the program, the contractor will deliver the budget impact models for the SI and FAST products. These products will be modeled individually as well as incrementally. The final models will be share with BARDA in MS Excel format. (WBS 2.1.25.2)

- The final deliverable for this program will consist of an app-based, customer-facing ROI calculator leveraging the excel output described above, which can be used with payers and other potential customers to engage in value discussions. (WBS 2.1.25.3)

2.7.3 Timing

Immediately following the 3rd party market research, the contractor will proceed to engage a supplier (subcontractor) to generate the cost effectiveness analysis study and the budget impact modeling per each of the products. The app-based, customer-facing ROI calculator will be created once the models are final. The duration of this work is estimated at 6-9 months.

The supplier (subcontractor) is:

Stacey Kowal
Practice Leader, Health Economics Modeling
Health Economics & Outcomes Research &
Real World Evidence Solutions
IQVIA

3. (CLIN 0002) PRODUCT 2: FAST Exam (FE)

The purpose of this task is to develop, and submit to the FDA for 510(k) clearance, a multi-functional hand-held Lumify device for automated image acquisition and interpretation during an AI-based FAST exam. This task includes the development of a new-to-the-world 3D ultrasound transducer, a clinical AI software application, and three studies.

Summary of Product Development, including M3D: The overall product development strategy for the Fast Exam product follows Philips standard Research and Development framework and processes. There are two parallel work streams of development activities: the one for the Mobile 3D (M3D) HW/SW system and the one for the standalone FAST AI algorithm. The two work streams will merge in year 4 to create the FAST Exam (FE) system product release. **Advance Development** is the initial phase of product development (Year 1-2 for M3D, Year 1-3 for FAST AI). The main goal is to prove concepts, de-risk, and solidify requirements within each of these functional areas. The M3D system has five work streams of concurrent engineering activities: sensor, HW, transducer assembly and test, SW development & test, and clinical evaluation. The FAST AI work streams are AI algorithm development, clinical 3D data collection, and annotation. For clinical 3D data collection, the Philips EPIQ 3D commercially available system will be used for the AI data collection while the M3D system development is happening in parallel.

The next phase, **Product Development** (Year 3-4 for M3D, Year 4-5 for FE) is the commercial development phase. The goal is to develop the product through commercialization, utilizing the Philips Product Development Launch and Maintain (PDLM) process. The work streams from the Advance Development phase move into product development work streams. The development strategy is to release the M3D product prior in year 4. The M3D image data will then be used to train and verify the FAST AI algorithm. The final FAST AI algorithm will be merged into the system platform as part of the FE product development for the final product validation.

Summary of Clinical Studies: Two studies are envisioned in the years 1-3 (base years): a pre-clinical study (FE2) for abdominal trauma/bleeding (18 animals) and a clinical study (FE9) with 417 patients. For the second study, after collecting data from 20 healthy volunteers, a meeting with the FDA will be planned to obtain feedback on the study. The study will then continue for the remaining patients. These studies will be conducted using available ultrasound systems (specifically, EPIQ 3D).

In years 4 and 5 (option years), an additional study (FE23) involving 408 patients with abdominal blunt trauma/bleeding will be conducted, using the novel 3D transducer (mobile 3D, M3D). For this third study, after collecting data from 30 patients, a meeting with the FDA will be planned to obtain feedback on the study. Please see Section 8 of this document for a details of clinical studies. In the following a short paragraph of each study is presented, along with information on CROs.

- **STUDY 5: Pre-clinical Abdominal Trauma/Bleeding Injury for image acquisition, analysis, and correlation to pathology using commercially available transducers (FE Task 1.1.a)** A pre-clinical swine study (n=18 animals) of blunt force traumatic injury and severe bleeding that has been previously developed at

OHSU for DoD trauma studies will be performed to establish baseline image quality and transducer requirements for developing 3D transducer hardware. After institutional approvals, anesthetized domestic swine will be instrumented with arterial and venous lines for monitoring hemodynamics status. Serial 100 ml aliquots of anticoagulated swine whole blood will be instilled into the peritoneal cavity with serial FAST ultrasound imaging protocols using commercial Philips system EPIQ-7 and transducers performed with up to a total of 1 liter of blood. Subsequently, swine with lacerations of the liver made through at least one major vessel through a 2-cm incision in the right upper quadrant of the abdomen will be studied. These animals will be euthanized at 30-minute intervals and blood recovered and measured after euthanasia. The ultrasound images collected in this study will be annotated and used for algorithm development and to generate input for design of volunteer and patient studies.

- **STUDY 6a. Healthy volunteer data collection using commercially available transducers (FE Task 1.1.b)** This study will establish a high-quality, expert-level Ultrasound image library of abdominal images of healthy volunteers to enable AI-based training of image parameters and standardized views in ultrasound images and collect requirements for transducer development. Healthy volunteers (n=20) will be recruited under an approved IRB that assures safety and privacy. The images will be collected using X5-1 Cardiac transducer (hardware basis for development of FWP) on the Philips premium platform EPIQ-7, C5-2 abdominal transducer on Lumify platform (or any additional commercially available Philips transducers, if needed). The data will be acquired using different image acquisition parameters per predefined protocol. The parameters will be recorded and associated with images acquired, and will provide input for the study on patients.

- **STUDY 6b: Clinical Abdominal Blunt trauma/bleeding image acquisition – data collection (FE Task 1.1.c):** The objective of this study will be to build a high-quality image library of patients with blunt, closed-abdominal trauma and bleeding using the 3D FWP. Studies will be performed at the trauma and emergency departments at OHSU, Womack Army Hospital-Fort Bragg, Brooke Army Medical Center, Tripler Army Medical Center and Washington Hospital in Washington DC. Initial studies will evaluate settings and imaging protocols for the new 3D transducer. Emergency room protocols will be developed for acquiring ultrasound FAST exams (n=417 patients) along with conventional clinical studies and follow-up post-surgical intervention, if indicated, will establish ground truth necessary for optimal image annotation and machine learning for algorithm development.

- **STUDY 7. Clinical Validation for FAST (FE Task 5.2):** The objective of this study is to validate, in a prospective clinical study that the integrated device, FAST AI software with 3D Transducer on Lumify platform improves (1) sensitivity and specificity, (2) exam time and (3) experience of staff, compared to standard exam with 2D transducer without AI support. Studies will be done at the trauma and emergency departments at OHSU, Womack Army Hospital-Fort Bragg, Brooke Army Medical Center, Tripler Army Medical Center and Washington Hospital in Washington DC. Patients admitted to the hospital emergency room with closed abdominal trauma and suspected of having intra-abdominal bleeding will be screened for inclusion and exclusion criteria. If the attending physician determines that the patient is an appropriate candidate an informed consent will be obtained. All

enrolled subjects will undergo 2D FAST exams performed according to ER and ultrasound manufacturer specifications and a 3D FAST exam using the FWP within one hour of each other in either order. All 2D and 3DL FAST images will be sent to OHSU where images will be evaluated for quality and analyzed for acceptance by experts. Subjects' medical records on days 2, 5, and 10 following FAST assessment on day 1 such as clinical diagnosis of abdominal bleeding (or negative), occurrence of surgical or endoscopic laparotomy, and MRI if performed as part of routine care will be reviewed to correlate with ultrasound findings. It is expected that about 408 patients may be enrolled in this study, with exact numbers chosen based on power analysis using data from earlier studies.

Summary of AI Automation Algorithms for FAST Exam: The AI automation has two major components: (1) automation of acquisition, which may include selection of imaging parameters and selection of 2D/3D views; and (2) automation of interpretation, which may include binary classification of images (positive = blood pool, negative = no blood pool) and selection of a bounding box around the blood pool. The acquisition and interpretation are not independent; the interpretation informs the acquisition process, e.g. plane selection. The first version of the AI algorithm (version 1) will be developed based on pre-clinical images (first study FE2) and clinical images (second study FE9). It will be further refined (version 2) based on clinical FAST imaging data collection (second study FE9) and data collected with M3D (third study FE23). Validation studies will be conducted with sequestered data, not used in developing either version of the algorithm.

Summary of FDA Meetings: Related to regulatory milestones, over the course of this timeline, the following meetings will be scheduled: An FDA pre-meeting by the end of year 1 (for the second study, after collecting data for 20 patients), an FDA pre-submission meeting within year 3 (to present update of second study FE9 and get FDA feedback on study protocol for the third study FE23). Should a Go decision be made by the end of year 3, the contractor envisions FDA 510(k) submissions for a standalone FE AI algorithm in year 4, for an M3D ultrasound system also in year 4, and an FE Lumify product in year 5. Philips envisions an additional FDA pre-meeting in year 4 (for the third study FE23, after collecting data from 30 patients using M3D) to get FDA feedback before the third study ramps up for 300 patients.

Summary of Deliverables: The following section outlines several key deliverables that are also listed in 4.1 Contract Deliverables. Prior to each study, a study protocol will be submitted for BARDA to review and approve.

Specific to year 1, among the key deliverables, but not inclusive of all, are: completion of a pre-clinical animal imaging study of abdominal bleeding, the start of EPIQ 3D human data collection, completion of an annotated library of high quality pre-clinical human images with and without blood pooling, both onset and successful management of a single site clinical imaging study of normal and abdominal bleeding patients and of the development of FAST AI algorithms and the completion of both a preliminary plan for AI algorithm architecture and a technical report on image quality and transducer requirements for hardware.

Among key deliverables for year 2 are: onset of clinical annotation for machine learning, such that there is a completion of a Version 1 of a detection and diagnosis algorithm and of

an acquisition automation algorithm validated on clinical images, completion of an FWP approved for human scan and clinical testing followed by onset and successful management of a clinical imaging study with 3D FWP in patients with abdominal trauma, a proposed transducer and system architecture for a commercial product and a preliminary report completed on the feasibility of FAST AI in human data and a development strategy.

Key year 3 deliverables include: a first version of all AI algorithms, completion of the data collection portion of a 3D FAST imaging study in patients with abdominal trauma, the start of a product development process and the eventual submission of materials in support of a FDA pre-submission meeting to establish a regulatory path for FDA allowance of an algorithm for a FAST Exam standalone app.

Among Year 4 deliverables, if a Go decision is made, are: Preparation and submission of mobile 3D FDA 510(k) documents, clinical annotation for machine learning, including training and verification of algorithms, that results in the final version of all AI algorithms, the design of a validation study with FAST AI and completion of reports on the clinical imaging study and on Al development in preparation for a FDA 510(k) application for a FAST Exam. Year 5 deliverables, if a Go decision is made, are: Reports with evidence of FAST Al design validation, results from a FAST Al M3D clinical validation study with 300 patients, the delivery of a commercially viable software platform and viable AI algorithms for FAST Exam and a final system integration and manufacturable product.

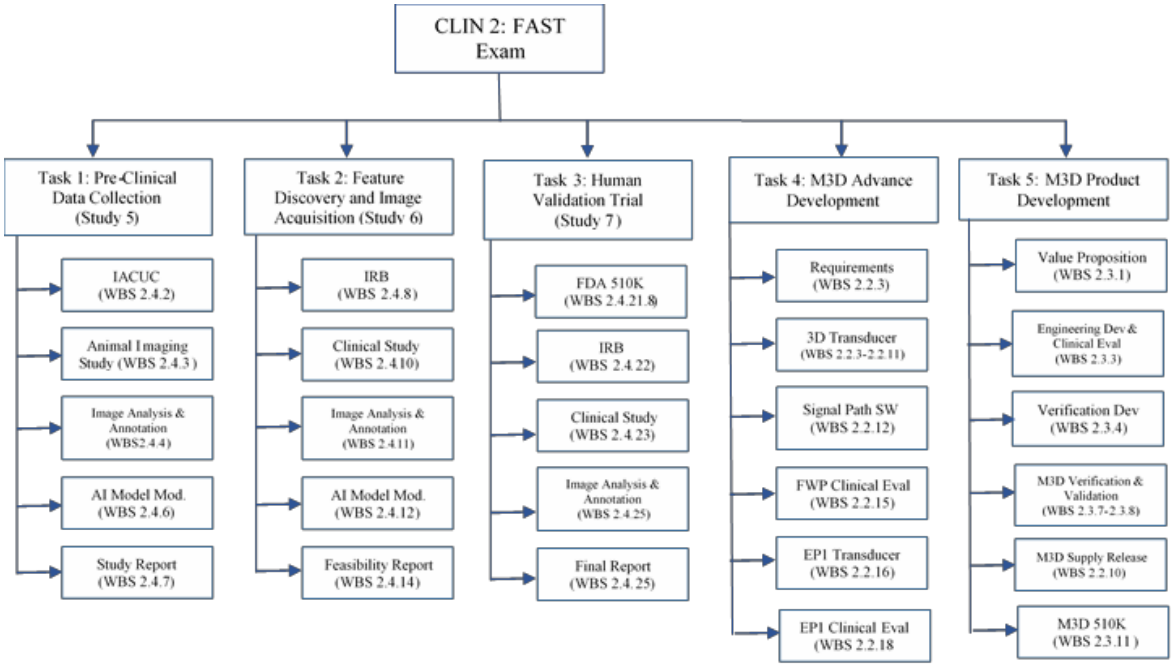

Figure 2: Activity Diagram Showing Key Activities in the Development of FAST Exam Product

3.1 Contract Deliverables for PRODUCT 2: FAST Exam (FE)

WBS #	Unique Number	Deliverable Description	Year
2.2.1.16	FE-D-1	Summary of development highlights: Sensor, acquisition HW, Transducer Assembly, and SW.	Year 1

2.2.11.8	FE-D-2	Design and fabrication of five (5) FWP transducer.	Year 1
2.2.13.2	FE-D-3	Transducers integrated into the Lumify SW with 3D Planar imaging.	Year 1
2.2.13.7	FE-D-4	System integration early test results: Acoustic, electrical, thermal, reliability.	Year 1
2.2.3.8	FE-D-5	Proposed sensor and transducer architecture for EP.	Year 1
2.2.3.9	FE-D-6	HW/ASIC/SW signal path defined for EP.	Year 1
2.2.3.9	FE-D-7	API specifications defined for EP.	Year 1
2.2.1.20	FE-D-8	A technical report on image quality and transducer requirements for HW.	Year 1
2.4.3	FE-D-9	Pre-clinical animal imaging study of abdominal bleeding (Study 5)	Year 1
2.4.4	FE-D-10	Complete annotations for set of pre-clinical images.	Year 1
2.4.5	FE-D-11	Preliminary AI algorithm architecture.	Year 1
2.4.6	FE-D-12	Version 1 of detection and diagnosis algorithm validated on pre-clinical images.	Year 1
2.4.7	FE-D-13	Report of animal imaging study and AI development	Year 1
2.4.2.8	FE-D-14	Submit study protocol to BARDA for review and approval	Year 1
2.4.10.1	FE-D-15	Single site clinical imaging study of normal patients (Study 6)	Year 1
2.4.11.1	FE-D-16	Labelled library of clinical images.	Year 1
2.1.1.1.2	FE-D-17	M3D Requirements for API development.	Year 1
2.4.5.3	FE-D-18	Requirements for lumify product for FAST Exam	Year 1
2.4.5.6	FE-D-19	Report analyzing product risk for lumify product for FAST Exam	Year 1
2.2.2.17	FE-D-20	Summary of advanced development conclusions.	Year 2
2.2.15.7	FE-D-21	FWP approved for human scan and clinical testing.	Year 2
2.2.16.6	FE-D-22	Design and fabrication of ten (10) EP transducers.	Year 2
2.2.17.1	FE-D-23	Transducers integrated into the Lumify SW with 3D Volume imaging and API/SDK SW.	Year 2
2.2.17.7	FE-D-24	System Integration EP test results: Acoustic, electrical, thermal, reliability.	Year 2
2.2.17.8	FE-D-25	Proposed transducer and system architecture for the commercial product.	Year 2
2.4.8.1	FE-D-26	Preparation and Submission of IRB documents to perform human FAST Exam	Year 2
2.4.8.6	FE-D-27	Submit study protocol to BARDA for review and approval	Year 2
2.4.10	FE-D-28	Clinical imaging study with 3D FWP in patients with abdominal trauma.	Year 2
2.4.11.2	FE-D-29	Labelled library of clinical images	Year 2
2.4.13	FE-D-30	Version 1 of acquisition automation algorithm validated on clinical images.	Year 2
2.2.3.4	FE-D-31	Refined requirements for transducer development.	Year 2

2.2.19.6	FE-D-32	EP Clinical test results.	Year 3
2.3.1.14	FE-D-33	Concept and requirements defined - VPA milestone achieved.	Year 3
2.3.7.14	FE-D-34	A report summarizing design of the verification testing	Year 3
2.2.3.33	FE-D-35	Project plan - PDC milestone.	Year 3
2.3.3	FE-D-36	EP2 Engineering Development	Year 3
2.3.3.6		a. Support& Manage Build EP2 Sensors, transducer	Year 3
2.3.3.5		b. Engineering Prototype (EP) Acquisition Software development	Year 3
2.3.3.5.6		c. Software application for retrieving ultrasound imagery from the Lumify application via the created API and storing these images on a file system	Year 3
2.3.3.6	FE-D-37	System process development start	Year 3
	FE-D-38	First version of all AI Algorithms.	Year 3
2.4.14	FE-D-39	Preliminary report of feasibility of FAST AI in human data	Year 2
2.4.14.4	FE-D-40	Preparation and submission of materials in support of FDA Pre-Submission meeting, to establish regulatory path for FDA allowance of algorithm for FAST Exam stand alone app. BARDA go-nogo decision	Year 3
2.3.7.14	FE-D-41	Clinical testing showing proof of meeting mobile 3D system requirements.	Year 4
2.3.3.9.3	FE-D-42	Transducer VRR review - Final design with release into Quality System	Year 4
2.3.4.2	FE-D-43	Verification Transducer (VT) build and test.	Year 4
2.3.4.11	FE-D-44	Verification Prototype (VP) Software release.	Year 4
2.3.6.1	FE-D-45	Production Transducer (PT) release / SP release.	Year 4
2.3.7	FE-D-46	Start of Verification (SVER) with Mobile 3D system	Year 4
2.4.16	FE-D-47	Version 2 of detection and diagnosis algorithm validated on clinical images.	Year 4
2.4.17	FE-D-48	Version 2 of acquisition automation algorithm validated on images.	Year 4
2.4.18	FE-D-49	Preparation and submission of Mobile 3D FDA 510k documents.	Year 4
2.4.20	FE-D-50	Final version of all AI algorithms.	Year 4
2.4.21.8	FE-D-51	Produce report of clinical imaging study and Al development in preparation for FDA 510K application for FAST Exam.	Year 4
2.4.24	FE-D-52	Conduct Prospective clinical trial to validate AI 3D Fast algorithm	Year 5
2.4.21.5	FE-D-53	Delivery of commercially viable software platform and prototype. Integrated Product and design (Product development, PLC)	Year 5
2.4.21.4.4	FE-D-54	Delivery of commercially viable AI algorithms for FAST Exam.	Year 5

2.4.217	FE-D-55	FE System Release (RA, SR, RFD). Final system Integration and manufacturable product.	Year 5

3.2 Task 1: Pre-Clinical Data Collection (Study 5)

Subtask Purpose	Deliverables (Year)
Conduct a pre-clinical study for collection of image data that will be used in AI Algorithm development for FAST Exam.	FE-D-9 – FE-D-13 (Year 1)

3.2.1 Pre-clinical Abdominal Trauma/Bleeding Injury for image acquisition, analysis, and correlation to pathology using commercially available transducers (FE Task 1.1.a.)

- The contractor shall prepare and submit IACUC for animal abdominal bleeding 3D FAST imaging study (WBS 2.4.2/FE1)
- The contractor shall Conduct Animal Imaging Study (WBS 2.4.3/FE2), the output of which is: (1) A library of high-quality images with and without blood pooling available for annotation. (2) A report of image quality and transducer requirements. (3) Input for design of volunteer and patient studies.

3.2.2 Image Analysis and Annotation for Image Library for AI (for animal data) (FE Task 1.1.d).

- The contractor shall perform image analysis and annotation of animal imaging study (WBS 2.4.4/FE3)

3.2.3 Automatic Detection and Diagnosis of Pooled Blood in the Abdomen from Animal Data (FE Task 1.2.a)

- The contractor shall develop preliminary AI algorithm architecture (WBS 2.4.5/FE4)
- The contractor shall validate Version 1 of detection and diagnosis algorithm on pre-clinical (animal) images (WBS 2.4.6/FE5)

3.2.4 Automation of Image Acquisition from Animal Data (FE Task 1.2.b)

- The contractor shall develop preliminary AI algorithm architecture (WBS 2.4.5/FE4)
- The contractor shall validate Version 1 of image acquisition algorithm on pre-clinical (animal) images (WBS 2.4.6/FE5)
- The contractor shall produce a report of animal imaging study and AI development (WBS 2.4.7/FE6)

3.3 Task 2: Clinical Study Feature Discovery and Image Acquisition (Study 6)

Subtask Purpose	Deliverables (Year)
Conduct clinical studies, first using healthy volunteers, then with patients with abdominal bleeding, to gather image data to be used in AI algorithm development.	FE-D-15 – FE-D-16 (Year 1) FE-D-26 – FE-D-30 (Year 2)

3.3.1 Healthy Volunteer Data Collection Using Commercially Available Transducers (Study 6a) (FE Task 1.1.b.)

- The contractor shall prepare, submit and get approval from Institutional Review Board (IRB) for human 3D FAST imaging study of healthy human volunteers (WBS 2.4.8/FE7)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.4.8.6)
- The contractor shall train clinical site and initiate tasks for 3D FAST imaging study of healthy human volunteers (WBS 2.4.9/FE8)

3.3.2 FE Task 1.1.c, FE Task 2.1.c, FE Task 3.1.c: Clinical Abdominal Blunt Trauma/Bleeding Image Acquisition (Study 6b)

- The contractor shall prepare and submit IRB documents and get approval for human FAST imaging study of abdominal trauma and bleeding (WBS 2.4.8/FE7)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.4.8.6)
- The contractor shall train clinical site and initiate tasks for 3D FAST imaging study of abdominal trauma and bleeding (WBS 2.4.9/FE8)
- The contractor shall conduct clinical imaging study of abdominal trauma and bleeding (WBS 2.4.10/FE9)

3.3.3 Image Analysis and Annotation for Image Library for AI. (FE Task 2.1.d.)

- The contractor shall perform image analysis and annotation for the clinical imaging study (healthy volunteers) (WBS 2.4.11/FE10)

3.3.4 Development and Validation of Automatic Detection and Diagnosis of Pooled Blood in the Abdomen Using Clinical Data (FE Task 3.2.a.)

- The contractor shall develop modification of swine algorithm using human images of abdominal trauma and bleeding (WBS 2.4.12/FE11)
- The contractor shall prepare and submit a preliminary report of feasibility of FAST AI in human data (WBS 2.4.14/FE13)
- The contractor shall validate Version 2 of the detection and diagnosis algorithm on human images (WBS 2.4.16/FE15)

3.3.5 Development and Validation of Image Acquisition Automation Using Clinical Data (FE Task 3.2.b)

- The contractor shall validate Version 1 of the acquisition automation algorithm on human images (WBS 2.4.13/FE12)
- The contractor shall validate Version 2 of the acquisition automation algorithm on human images (WBS 2.4.17/FE16)

3.3.6 Mobile 3D System Product Development (M3D Task 3.0)

- The contractor shall produce and submit materials for FDA Pre-Submission meeting to establish regulatory path for AI 3D FAST algorithm for abdominal

trauma/bleeding (WBS 2.4.18/FE17 and MVP22)

- The contractor shall provide written response to FDA Pre-Sub meeting (WBS 2.4.19/FE18)

3.4 Task 3: Clinical Validation Studies (Study 7)

Subtask Purpose	Deliverables (Year)
Conduct Clinical Validation Study.	FE-D-47 – FE-D-52 (Years 4 and 5)

3.4.1 Clinical Validation Study (FE Task 5.2) (Study 7)

- The contractor shall prepare, submit and get approval from Institutional Review Board (IRB) for FDA clinical validation trial sites (WBS 2.4.22/FE21)
- The contractor shall submit study protocol to BARDA for review and approval (FE-D-32)
- The contractor shall train clinical site and initiate 3D FAST imaging study of abdominal trauma and bleeding (WBS 2.4.23/FE22)
- The contractor shall conduct prospective clinical trial to validate AI 3D FAST algorithm in patients with suspected abdominal trauma/bleeding (WBS 2.4.24/FE23)

3.4.2 Clinical Validation (FE Task 5.2.)

- The contractor shall provide a final version of all AI algorithms for the clinical trial (WBS 2.4.20/FE19)
- The contractor shall perform clinical imaging annotation for abdominal bleeding injury validation trial (WBS 2.4.25/FE24)

3.5 Task 4: M3D Advance Development

Subtask Purpose	Deliverables (Year)
Development and testing of the Mobile 3D System and API Advanced Development.	FE-D-1 – FE-D-8 (Year 1) FE-D-17 – FE-D-19 (Year 1) FE-D-20 – FE-D-25 (Year 2) FE-D32 – FE-D-37 (Year 3)

3.5.1 Requirements for 3D Sensor and M3D Task 1.1.B.: 3D Signal Path Hardware (M3D Task 1.1.a.)

- The contractor shall develop System Project Plan, management, and design for first working prototype (FWP) – Year 1 (WBS 2.2.1/M3D1)
- The contractor shall develop System Project Plan, management, and design for first working prototype (FWP) – Year 2 (WBS 2.2.2/M3D2)
- The contractor shall provide a report of requirements and architecture (WBS 2.2.3/M3D3)

3.5.2 Transducer Assembly Development (M3D Task 1.1.c.)

- The contractor shall initiate ASIC design (WBS 2.2.4/M3D4)
- The contractor shall perform mechanical design (parts, interconnects, enclosures) (WBS 2.2.5/M3D5)
- The contractor shall perform acoustic design, material selection, characterization, specification (WBS 2.2.6/M3D6)
- The contractor shall conduct process development (WBS 2.2.7/M3D7)
- The contractor shall develop Transducer Test (WBS 2.2.8/M3D8)
- The contractor shall develop a printer circuit board HW (WBS 2.2.9/M3D9)
- The contractor shall develop FPGA firmware design (WBS 2.2.10/M3D10)
- The contractor shall develop FWP transducer assembly, thermal, reliability and assembly level (non-functional) testing (WBS 2.2.11/M3D11)

3.5.3 Signal Path Software Development (M3D Task 1.2.a.)

- The contractor shall develop software for signal acquisition (WBS 2.2.12/M3D12)

3.5.4 API Software Development (M3D Task 1.2.b.)

- The contractor shall develop M3D API Software requirements
- The contractor shall develop M3D API Software, test and validation

3.5.5 FWP System Integration and Testing (M3D Task 1.3.a.)

- The contractor shall perform FWP System integration and testing (WBS 2.2.13/M3D13)
- The contractor shall perform FWP Acoustics Optimization (WBS 2.2.14/M3D14)
- The contractor shall perform FWP Clinical Evaluation (WBS 2.2.15/M3D15)

3.5.6 EP System Integration (M3D Task 1.3.b.)

- The contractor shall perform EP1 Transducer assembly, Thermal, Reliability & Assembly level (non-functional) testing (WBS 2.2.15/M3D15)
- The contractor shall perform EP1 System Integration and Testing (WBS 2.2.16/M3D16)
- The contractor shall perform EP1 Acoustics Optimization (WBS 2.2.17/M3D17)
- The contractor shall perform EP1 Clinical Evaluation (WBS 2.2.18/M3D18)
- The contractor shall perform Advance Development Evaluation & Product Development Initiation (WBS 2.2.19/M3D19)

3.6 Task 5: M3D Product Development

Subtask Purpose	Deliverables (Year)
Mobile 3D System Product Development	FE-D-41 – FE-D-46 (Year 4) FE-D-53 – FE-D-55 (Year 5)

3.6.1 Mobile 3D System Product Development (M3D Task 3.0)

- The contractor shall develop project plan for full program through commercial

release (WBS 2.2.20/M3D20)

- The contractor shall perform EP2 Engineering Development (WBS 2.2.21/M3D21)
- The contractor shall perform VT/VP Engineering Development (WBS 2.2.22/M3D22)
- The contractor shall perform Product Launch Commit (PLC) (WBS 2.2.23/M3D23)
- The contractor shall perform PT/PP Engineering Development (WBS 2.2.24/M3D24)
- The contractor shall perform Start of Verification (SVER) (WBS 2.2.25/M3D25)
- The contractor shall perform Start of Validation (SVAL) (WBS 2.2.26/M3D26)
- The contractor shall perform Released for Acquisition (RFA) (WBS 2.2.27/M3D27)
- The contractor shall perform Supply Released (SR) (WBS 2.2.28/M3D28)
- The contractor shall prepare FDA 510(k) Submission (WBS 2.2.29/M3D28)

4. (CLIN 0003) PRODUCT 3: EPIQ-7/Compartment Syndrome (E/CS)

The purpose of this task is to perform a phase-one human clinical trial.

Summary of Clinical Studies: The phase-one human clinical proof of principle study of patients being evaluated for compartment syndrome injury of the lower extremity, correlation will be made between intra-compartment pressures measured in mmHg using a standard Stryker pressure gauge system, and Shear Wave Elastography (SWE) measurements of tissue stiffness in kPA and Micro-Flow Imaging (MFI) using a Philips EPIQ-7 ultrasound system with an eL 18-4 linear transducer. Goal for this study would be to recruit 341 patients (CS3).

In a phase-two prospective randomized, blinded clinical trial the accuracy of evaluation of diagnosis of compartment syndrome will compare measurements with SWE and MFI using an EPIQ 7 system with Stryker pressure measurements in a non-inferiority clinical trial design. Goal for this study would be to recruit 416 patients (CS12-CS13). Please see Section 8 of this document for a details of clinical studies.

- **STUDY 8: Clinical Proof principle study for diagnosis of compartment syndrome.** In this Phase-one human clinical proof of principle study of patients being evaluated for compartment syndrome injury of the lower extremity, correlation will be made between intra-compartment pressures using a standard Stryker pressure gauge system, and Shear Wave Elastography (SWE) measurements of tissue stiffness in kPA and micro-vessel blood flow using a Philips EPIQ-7 ultrasound system. The study sites include OHSU, Washington Hospital Center, University of Pittsburgh Medical Center, Womack Army Medical Center and Brooke Army Medical Center. Patients admitted to emergency rooms that are suspected of having acute lower extremity compartment syndrome where planned evaluation includes Stryker needle pressure gauge measurements will have contemporaneous measurements of Pressure, SWE and micro-flow imaging (MFI) that will be performed, correlated and compared to clinical variables. It is estimated that 341 subjects will be enrolled in order to have at least sufficient subjects diagnosed with compartment syndrome with a minimum of 30mmHg pressure in at least one

compartment. All EPIQ-7 2D, SWE and MFI images will be sent to OHSU where images are evaluated for quality and analyzed by physicians with established expertise in ultrasound musculoskeletal imaging, blinded to the clinical data. Correlation of EPIQ-7 with eL18-4 linear transducer SWE findings with microvascular flow imaging (MFI) will validate lack of small vessel flow and flow restoration following surgical fasciotomy in patients with compartment syndrome. Correlation with high-resolution MRI tissue scanningof the lower extremity compartments will also be performed if it does not delay emergent fasciotomy. Clinical outcomes will be collected by reviewing subjects' medical record on day 2, 5, and 10 following SWE assessment on day 1.

- **STUDY 9: Pivotal Prospective Clinical Validation Trial comparing SWE/MFI diagnosis of lower extremity compartment syndrome accuracy with Stryker Needle Gauge Pressure monitor.** If the Phase I proof of principle clinical trial demonstrates positive results a multi-center prospective clinical trial will be performed to validate SWE and MFI as non-inferior to conventional pressure gauge measurements for the diagnosis of lower extremity compartment syndrome. This will be a randomized, blinded study comparing accuracy of assessment of a projected total of 410 patients admitted to hospital emergency room with suspected lower extremity compartment syndrome. The sites include OHSU, Washington Hospital Center, Brooke Army Medical Center, University of Pittsburgh Medical Center, and Womack Army Medical Center. A Philips EPIQ7 ultrasound system with an eL18-4 transducer will be used to obtain SWE and MFI measurements. After informed consent, subjects will be randomized to undergo either the Stryker needle pressure gauge measurement or the ultrasound measurement. Clinicians will be blinded to the results of either test, and separate clinicians will perform each test. Procedures will be performed as contemporaneously as possible. SWE/MFI will also be performed on the contralateral leg for comparison. All EPIQ-7EPIQ-7 2D, SWE and MFI images will be sent to OHSU where images are evaluated for quality and analyzed by expert physicians. Clinical outcomes will be collected by reviewing subjects' medical record on day 2, 5, and 10 following SWE assessment on day 1. Data to be collected include clinical diagnosis of compartment syndrome, occurrence of fasciotomy, timing of fasciotomy, tissue appearance at fasciotomy, and MRI if performed as part of routinecare.

Summary of FDA Meetings: Regulatory milestones include an FDA pre-meeting in years 1 and 3 prior to any clinical validation study with the latter meeting involving submission of data and a marketing and sales plan.

Summary of Deliverables: To summarize the deliverables under 5.1 Contract Deliverables, the phase-one clinical trial will be completed along with image analysis and the design of a prospective clinical validation study from year 1 to 2 followed by a Go/No-Go decision by BARDA. At the time of that decision BARDA will have received clinical study results and the submission of a further study protocol along with a report of the expert analysis of 2D, SWE and MFI images.

Should a Go decision be made by BARDA, the clinical validation study will be conducted in years 3 through 5, following BARDA's review and approval of the study protocol. The

study will culminate in a study report and a device for procurement.

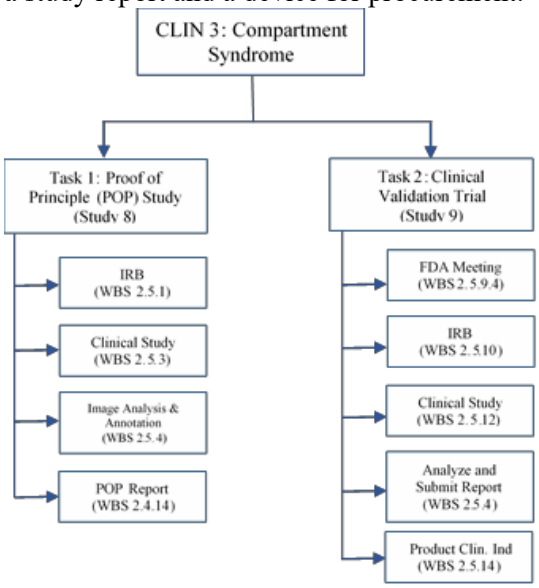

Figure 3: Activity Diagram Showing Key Activities in Compartment Syndrome Clinical Studies

4.1 Contract Deliverables for PRODUCT 3: EPIQ-7/Compartment Syndrome: (E/CS)

WBS	Unique Number	Deliverable Description	Year
2.5.1	CS-D-1.	IRB preparation and approval for Clinical Correlation and Proof of Principle Study.	Year 1
2.5.1.42	CS-D-2.	Submit study protocol to BARDA for review and approval	Year 1
2.5.3	CS-D-3.	Conduct clinical proof of principle study for diagnosis of compartment syndrome	Year 1
2.5.4	CS-D-4.	Report of expert image analysis of 2D, SWE and MFI images.	Year 2-3
2.5.6.1	CS-D-5.	Produce report of proof of principle CS clinical study BARDA go/no-go decision	Year 2-3
2.5.7	CS-D-6.	GO/NO-GO Meeting with BARDA, if "Go", proceed:	Year 3-4
2.5.8	CS-D-7.	Preparation and submission of materials for FDA designation meeting.	Year 3-4
2.5.9.4	CS-D-8.	Conduct FDA meeting	Year 3-4
2.5.10	CS-D-9.	IRB submission for Prospective Validation clinical trial.	Year 3-4
2.5.10.2	CS-D-10.	Submit study protocol to BARDA for review and approval	Year 3-5

2.5.12	CS-D-11.	Conduct clinical validation study for diagnosis of compartment syndrome	Year 3-4
2.5.12.6	CS-D-12.	Complete Prospective clinical validation trial.	Year 5
2.5.13	CS-D-13.	Compile and analyze clinical validation study data	Year 5
2.5.14	CS-D-14.	Product clinical indication development	Year 5

4.2 Task 1: Phase-one proof of principal clinical study (Study 8)

Subtask Purpose	Deliverables (Year)
Phase one clinical trial for compartment syndrome.	CS-D-1 to CS-D-5 (Year 1-3)

4.2.1 A POP Multi-Center Human Clinical Trial (E/CS Task 1.) (Study 8)

- The contractor shall submit and get IRB approval for clinical imaging trial sites (WBS 2.5.1/CS1)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.5.2/CS-D-2)
- The contractor shall prepare for the clinical trial including site training, equipment purchase and initiation of study at clinical sites (WBS 2.5.2/CS2)
- The contractor shall conduct clinical proof of principle study for diagnosis of compartment syndrome (WBS 2.5.3/CS3)
- The contractor shall perform expert image analysis of 2D, SWE and MFI images (WBS 2.5.4/CS4)
- The contractor shall compile and analyze proof of principle data (WBS 2.5.5/CS5)
- The contractor shall produce report of proof of principle compartment syndrome clinical study (WBS 2.5.6/CS6)

4.2.2 FDA Meeting (E/CS Task 2)

- The contractor shall produce and submit materials for FDA Device designation meeting (WBS 2.5.8/CS8)
- The contractor shall conduct the FDA meeting (WBS 2.5.9/CS9)

4.3 Task 2: Multi-Center Prospective Randomized Validation Study. (E/CS Task 3.) (Study 9)

Subtask Purpose	Deliverables (Year)
Phase two clinical validation for compartment syndrome.	CS-D-8 to CS-D-14 (Years 4-5)

4.3.1 Multi-Center Prospective Randomized Validation Study. (E/CS Task 3.)

- The contractor shall obtain IRB approvals for validation clinical trial (WBS 2.5.10/CS10)
- The contractor shall submit study protocol to BARDA for review and approval (WBS 2.5.10/CS-D-10)
- The contractor shall conduct clinical site training/initiation for validation study

(WBS 2.5.11/CS11)

- The contractor shall conduct clinical validation study for diagnosis of compartment syndrome (WBS 2.5.12/CS12)
- The contractor shall analyze clinical validation study data (WBS 2.5.13/CS13)

5. Cost Optimization Activities

Specific to the 3D transducer development, the contractor plans to initially re-use existing 3D sensor technology to accelerate the development of the overall solution. Philips plans to leverage the next generation transducer platform development that is currently underway, focused on improved cost position with minimum impact to performance.

As standard practice to product development, Philips engages in a process leveraging the DfX convention approach, which includes cross-functional involvement across the entire value chain.

The objective of this innovative approach is to unlock product cost reductions holistically, by looking into the way Philips designs, makes and delivers products and solutions, challenging all aspects of the value chain. Moreover, DfX stimulates multi-functional collaboration throughout Philips by starting with Cost Modeling and building on this with Design, Market, Manufacturing, Quality, Procurement, and Service aspects.

To be more specific, the cost reduction activity would focus on three areas:

1. Yield. Higher yield due to process improvement opportunities.
2. Materials. We would look for opportunities to reduce the raw material costs by working with our suppliers to identify opportunities, such as high volumens, created on their side.
3. Labor. Assembly labor is typically leaner over time due to process improvements and reductions in manufacturing overhead.

Through the lifecycle of the product, as new applications and new modes of usage of the 3D transducer are developed, the cost will be further reduced through increase in volume.

Here are the sections related to factory cost optimization, including hours.

M3D.3 Project Plan- Year 1

WBS	Task Name	Hours
2.2.1.12	Create Factory cost plan (includes BOM, labor, Yield& management)	160
2.2.1.15	Optimize factory cost plan	80

M3D.3 Project Plan- Year 2

WBS	Task Name	Hours
2.2.2.7	Create factory cost model (includes BOM, labor, yield and management)	20
2.2.2.15	On going factory cost plan	80

M3D.3 Requirements

WBS	Task Name	Hours
2.2.3.8	DfX Convention - Cross functional workshop focused on cost modeling	160

M3D.21 EP2 System Development

WBS	Task Name	Hours
2.3.3.6.9	DFX Convention - workshop focused on cost	320
2.3.3.6.10	EP2 cost optimization development - materials	800
2.3.3.6.11	EP2 cost optimization development - yield	800

To summarize the deliverables under 4.1 Contract Deliverables, the Phase One clinical trial will be completed along with image analysis and the design of a prospective clinical validation study from year 1 to 2 followed by a Go/No-Go decision by BARDA. At the time of that decision BARDA will have received clinical study results and the submission of a further study protocol along with a report of the expert analysis of 2D, SWE and MFI images.

Should a Go decision be made by BARDA, the clinical validation study will be conducted in years 3 through 5, following BARDA's review and approval of the study protocol. The study will culminate in a study report and a device for procurement.

Regulatory milestones include an FDA pre-meeting in years 1 and 3 prior to any clinical validation study with the latter meeting involving submission of data and a marketing and sales plan.

6. Study Details (SI8, SI18, FE9, FE23, CS3, CS12)

We summarize the Clinical Studies in this section, and also enumerate our assumptions.

Num.	Brief Study Description	Study ID	Num. of Patients	Enrollment Duration	Study Duration
1	SI8.Conduct acute smoke inhalation injury clinical imaging study	Study 2	137	2 years	2.5 years
2	SI18. Conduct Prospective clinical trial to validate AI program and algorithm in patients with suspected smoke inhalation injury	Study 3	160	2 years	2 years
3	FE9. Conduct clinical imaging study of abdominal trauma and bleeding	Study 6	417	2.25 years	3 years
4	FE23. Conduct Prospective clinical trial to validate AI 3D FAST algorithm in patients with suspected abdominal trauma/bleeding	Study 7	408	2 years	2.25 **years**
5	CS3. Conduct clinical proof of principle study for diagnosis of compartment syndrome	Study 8	341	2.0 years	2.25 years
6	CS12. Conduct clinical validation study for diagnosis of compartment syndrome	Study 9	416	2 years	2.5 years

Assumptions:

1. Numbers of patients/exams shown herein do not represent final net exams that are chosen for machine learning/testing, FDA validation studies. Exams shown above can be rejected for image quality, QC for clinical dx or data, or lack of desired UTZ features.

2. Smoke inhalation numbers are less because smoke inhalation lung injury is not common. We believe that these numbers may be sufficient for algorithm retraining to reach accuracy targets for detection of smoke inhalation injury because we begin with lung injury algorithms that are robust and accurate for at least 2 known features for inhalation lung injury and inflammation lung injury: consolidation and pleural effusion. Another known LUS feature associated with inhalation injury is B Lines for which a very accurate algorithm for detection was constructed during work supported by DARPA. Retraining the DARPA algorithm(s) for detection of smoke inhalation injury would only need re-training for merged B lines and any new features that are detected during the course of research proposed herein.
3. Numbers in summary tables do not include a much larger number patients screened, enrolled and imaged. Many patients will have negative ultrasound exams for desired features and excluded for inclusion in curated image library for annotation and machine learning training, testing and validation. Summary table patient/exam numbers project estimates of studies positive for findings or features.
4. Patient numbers and timelines/budgets have no contingency planning or budgeting for COVID 19 impacts on clinical study performance, timelines or costs and only reflect proposal planning up to Dec 8, 2019.

A detailed enrollment plan for each study, for each clinical site is provided below.

		Year 1				Year 2				Year 3				Year 4				Year 5			
		Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q	Q
Clinical Study	**Enrollent by Site**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Study 2: SI8.Conduct acute smoke inhalation injury clinical imaging study	BAMC					3	4	3	4	3	4										
	Medstar Washington Hosp Ctr			3	4	3	4	3	4	3	4										
	Wake Forest			2	2	2	2	2	2	2	2										
	Tualatin Valley Fire & Rescue			3	3	3	3	3	3	3	3										
	Portland Fire Dept					6	6	6	6	6	6										
	US Forest Service					2	2	2	2	2	2										
	Subtotal			**8**	**9**	**19**	**21**	**19**	**21**	**19**	**21**										
Study 3: SI18. Conduct Prospective clinical trial to validate AI program and algorithm in patients with suspected smoke inhalation injury	BAMC											3	4	3	4	3	4	3	4		
	Medstar Washington Hosp Ctr											3	4	3	4	3	4	3	4		
	Wake Forest											2	2	2	2	2	2	2	2		
	Tualatin Valley Fire & Rescue											3	3	3	3	3	3	3	3		
	Portland Fire Dept											6	6	6	6	6	6	6	6		
	US Forest Service											2	2	2	2	2	2	2	2		
	Subtotal											**19**	**21**	**19**	**21**	**19**	**21**	**19**	**21**		
Study 6: FE9. Conduct clinical imaging study of abdominal trauma and bleeding	BAMC					10	12	12	12	12	12	12	12								
	OHSU				10	12	15	15	15	15	15	15	15								
	TAMC					4	6	6	6	6	6	6	6								
	WAMC					4	6	6	6	6	6	6	6								
	Medstar Washington Hosp Ctr				10	10	12	12	12	12	12	12	12								
	Subtotal				**20**	**40**	**51**	**51**	**51**	**51**	**51**	**51**	**51**								
Study 7: FE23. Conduct Prospective clinical trial to validate AI 3D FAST algorithm in patients with suspected abdominal trauma/bleeding	BAMC													12	12	12	12	12	12	12	12
	OHSU													15	15	15	15	15	15	15	15
	TAMC													6	6	6	6	6	6	6	6
	WAMC													6	6	6	6	6	6	6	6
	Medstar Washington Hosp Ctr													12	12	12	12	12	12	12	12
	Subtotal													**51**	**51**	**51**	**51**	**51**	**51**	**51**	**51**
Study 8: CS3. Conduct clinical proof of principle study for diagnosis of compartment syndrome	OHSU		9	9	9	9	9	9	9	9											
	University of Pittsburgh		9	9	9	9	9	9	9	9											
	TAMC					10	10	10	10	10											
	BAMC					9	9	9	9	9											
	Medstar Washington Hosp Ctr		9	9	9	9	9	9	9	9											
	WAMC					6	6	6	6	6											
	Subtotal		**27**	**27**	**27**	**52**	**52**	**52**	**52**	**52**											
Study 9: CS12. Conduct clinical validation study for diagnosis of compartment syndrome	OHSU												9	9	9	9	9	9	9	9	
	University of Pittsburgh												9	9	9	9	9	9	9	9	
	TAMC												10	10	10	10	10	10	10	10	
	BAMC												9	9	9	9	9	9	9	9	
	MEDSTAR Washington Hosp Ctr												9	9	9	9	9	9	9	9	
	WAMC												6	6	6	6	6	6	6	6	
	Subtotal												**52**	**52**	**52**	**52**	**52**	**52**	**52**	**52**	

Contents

ATTACHMENT #2
INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All government contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number

or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request. Include numbering in format of year_month #.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost see the HHS *Contractor's Guide for Control of Government Property (https://archive.org/details/contractorsguide00unit)* (e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) Grand Totals

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

“I hereby certify that the salaries billed in this payment request are in compliance with the HHS Salary Rate Limitation Provisions in Section H of the contract.”

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

Attachment 3 - SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MGMT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515 (b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:**_____ **DUNS or DUNS+4:** _____	(c) Invoice/Financing Request No.: _____ (d) Date Invoice Prepared: _____ (e) Contract No. and Order No. (if applicable): _____ _____ (f) Effective Date: _____ (g) Total Estimated Cost of Contract/Order: _____ (h) Total Fixed-Fee (if applicable): _____ (i) ☐ Two-Way Match: _____ ☐ Three-Way Match: _____ (j) Office of Acquisitions: _____ (k) Central Point of Distribution: _____

(l) This invoice/financing request represents reimbursable costs for the period from_____ to _____

Expenditure Category* A	Cumulative Percentage of Effort/Hrs.		Amount Billed		Cost at Completion F	Contract Amount G	Variance H
	Negotiated B	Actual C	(m) Current D	(n) Cumulative E			
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							

(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____

(Name of Official) (Title)

* Attach details as specified in the contract

Attachment 4

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiat	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

Attachment 5
INSTRUCTIONS FOR COMPLETING
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by the Government in monitoring the application of financial and personnel resources to the BARDA funded contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) Total Costs to the Government.

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Attachment 6 INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:	
Total Enrollment:	**Protocol Number:**
Contract Number:	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

Attachment 7 - Research Patient Care Costs

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.

(c) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Attachment 8 - Report of Government Owned, Contractor Held Property

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY	
CONTRACTOR:	**CONTRACT NUMBER:**
ADDRESS:	**REPORT DATE:**
ADDRESS1:	
ADDRESS2:	**FISCAL YEAR:**
CITY:	
STATE:	
ZIP:	

CLASSIFICATION	BEGINNING OF		ADJUSTMENTS			END OF PERIOD	
	#ITEMS	VALUE	GFP ADDE	CAP ADDE	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST							
PROPERTY UNDER CONST							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP							
SPECIAL TEST EQUIP							
AGENCY PECULIAR							
AGENCY PECULIAR							
MATERIAL >=$25K							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							

SIGNED BY:			
SIGNATURE		DATE SIGNED:	
NAME PRINTED		Email	
TITLE		TELEPHONE	

End of Contract No. 75A50120C00097